THE MERCOSUL AND THE LIBERALISATION OF INTERNATIONAL TRADE: AN ANALYSIS OF THE ISSUES ON PATENT PROTECTION

Eugênio da Costa e Silva

Ph.D.
The University of Edinburgh
1996

I hereby declare that the present thesis
was composed by myself.

Tokyo, June 1996

Eugênio da Costa e Silva

For Genny da Costa e Silva,
my aunt, with love and respect

UNIVERSITY OF EDINBURGH

ABSTRACT OF THESIS (Regulation 3.5.10)

Name of Candidate Eugenio da Costa e Silva

Degree Ph.D. *Date* 30 June 1996

Title of Thesis The MERCOSUL and the Liberalisation of International Trade: An Analysis of the Issues on Patent Protection

No. of words in the main text of Thesis 112,322

On 26 March 1991 the integration process for approximating the markets of the four countries of the Southern Cone of Latin America was put into practice through the signing of the Treaty of Asuncion by Argentina, Brazil, Paraguay and Uruguay. This has proved to be the most prominent integrating initiative among developing countries.

Alongside contemporary discussion relating to integrating projects, intellectual property protection has also been of great concern to developing economies. It seems that boundaries in the modern world are no longer a geographic issue, but rather a political matter. It is of little doubt that the development of science and technology strategies will play a determinant part for social and economic development in the next century and beyond. Industrial property protection is necessarily the legal instrument which provides science and technology policies with a starting point.

This research intends to discuss these issues taking into account the legal aspects of patent protection in the context of the MERCOSUL. For this purpose the present study is divided into seven chapters. Chapter 1 provides a historical background of the process of Latin American integration, from LAFTA to MERCOSUL. Chapter 2 provides a general overview of the setting up of an international patent system, discussing the establishment and evolution of the Paris Convention and the setting up of "Trade-Related Aspects of Intellectual Property Rights" under the GATT auspices. These two chapters serve as an introductory background.

Chapters 3 and 4 examine the aspects of patent protection in the European Community. Chapter 3 discusses the legislative and juridical developments in the implementation of the principles of "free movement of goods" and "protection against unfair competition" *vis-a-vis* the exercise of patent rights within the Common Market. Chapter 4 reviews the attempt to unify patent rights in the Community by using the mechanism of inter-State Convention.

Chapters 5 and 6 evaluate more substantive aspects of patent rights in the international, supranational and national levels to draw up guidelines for the implementation of measures that should be taken into account by the MERCOSUL. Chapter 5 discusses primarily the protection of pharmaceutical products and processes, biotechnology and plant varieties. Chapter 6 analyses the application of the principles of free movement of goods and competition law in the MERCOSUL.

A complementary chapter is included to review the "biodiversity-related aspects of intellectual property rights". Chapter 7 utilises the wording of the Convention on Biological Diversity to investigate the following issues: access to genetic resources, technology transfer, biotechnology, and the protection of the knowledge and practices of local and indigenous communities.

The present research concludes by suggesting strategies for the setting of goals for national and regional science and technology as well as industrial policies for the MERCOSUL. It considers the harmonisation of national laws and of national juridical decisions within the integrated area as a prerequisite of implementing a common policy which will promote technological, economic and social development in the region.

TABLE OF CONTENTS

ACKNOWLEDGEMENTS

This research, done at the Faculty of Law of the University of Edinburgh, has been carried out with the help and assistance of several individuals and institutions.

I must thank, firstly, the "Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq)", a Brazilian public organ part of the Ministry of Science and Technology, for awarding me a scholarship to carry out the present research. I am also mostly grateful to the staff of CNPq who have been kindly dealing with the various problems of a student abroad.

I am also grateful to the Chamber of Deputies which allowed me to do the present research and continued to help me financially. It was in the Brazilian Parliament, I must say, that I learned how to work, how to understand, and how to believe in the future of my country and, above all, of Latin America.

At the Law Faculty of the Edinburgh University I would like to voice very special thanks to Professor Hector MacQueen, my supervisor, for his continuous assistance, his academic and personal concern for my thesis project, his support and his encouragement throughout these years. In addition, I wish to thank Dr. Robert Lane, my second supervisor, for introducing me to the issues on intellectual property protection within a Common Market. At the Faculty of Law I am also indebted to many of its staff, who helped me administratively and academically. My thanks go, particularly, to Adnan Amkhan, Andrew Scott, Lorna Paterson, Neil Walker, Nicholas Dyson, and the staff of the Law and Europa Libraries.

At the latest stage of my research, I have been awarded a Ph.D. fellowship at the Institute of Advanced Studies of the United Nations University, in Tokyo, Japan. I

am very grateful and honoured by that. This was an essential opportunity to develop further the environmental discussion of my thesis and to broaden my views on science and technology policies. At the UNU/IAS I wish to thank, in particular, Tarcisio Della Senta, Jyoti Parikh, Victor Kuipers and Jacob Park.

Several friends in Brazil and in Europe have been of great assistance, forwarding me information and necessary documents when requested, giving suggestions and helping me with infra-structure during my field research trips. Many of them have been helping me all the way through, from the very beginning, encouraging and supporting my project. To thank all I wish to list some. They are Carlos Eduardo Sette Camara, Carlos Navarro Gonzalez, Clausius Gonçalves Lima, Darrell Posey, Fernando Soares Lyra, Geraldo Torreão de Sá, Jairo Valadares, John Touchie, José Robalinho, Luciano Brandão, Manuel and Thais Cesário, Mauro Santayana, Michael Huber, Morten Plesner Smørdal, Ricardo Noblat, Roberto Battendieri, Romulo Sulz Gonsalves Júnior, Syleno Ribeiro de Paiva and Victor Allan.

I would like also to express my gratitude to all those who I have interviewed, asked for information or for any help during this period, either in Europe or in Brazil. Without exception all of them, in different situations, helped me without hesitation when I really needed it. They are listed below in Appendix VI.

Paulo Roberto de Almeida read carefully a substantial part of the first draft of the thesis and supplied me with very important insight, comments and information, in spite of his extremely busy life. I thank him most warmly for that.

I cannot forget the language assistance provided by Jill Knox. She revised the whole text of the thesis with great care and concern. Thank you Jill.

I must also express my love and gratitude to Anne, my wife, who has supported me all the way through with great respect towards my research, bearing patiently my constant absence due to the amount of work that I had to complete. Anne also helped me to organise the list of abbreviations. I would also like to thank my brother, Eduardo, for his encouragement and belief in all my projects. Last, but not least, I wish to thank my beloved parents, Meirione and Aluizio, for all the efforts that they have made throughout their lives to raise their children, for their love and, also, for their continuous support for my intellectual needs.

Needless to say, all the mistakes in this research remain my own responsibility.

Tokyo, June 1996

LIST OF ABBREVIATIONS

ABPI	Associação Brasileira de Propriedade Intelectual (Brazilian Association of Intellectual Property)
Berne Convention	Berne Convention for the Protection of Literary and Artistic Works
BILA	Boletim de Integração Latino-Americana
Biodiversity	Biological Diversity
BIRPI	United International Bureaux for the Protection of Intellectual Property
Brazilian Proposal	Proposta Brasileira de Acordo Visando à Harmonização de Leis em Matéria de Propriedade Industrial entre os Países Integrantes do Mercosul
Budapest Treaty	Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
CBD	Convention on Biological Diversity
CCM	Council of the Common Market (MERCOSUL)
CMG	Common Market Group (MERCOSUL)
CML Rev.	Common Market Law Review
CMLR	Common Market Law Reports
Convention on Jurisdiction and Enforcement	Convention on Jurisdiction and Enforcement of Judgment in Civil and Commercial Matters
COPAC	Common Appeal Court
Council for TRIPS	Council for Trade-Related Aspects of Intellectual Property Rights
CPC	Community Patent Convention (Convention for the European Patent for the Common Market) as amended by the Agreement Relating to Community Patents
CPC 1975	Community Patent Convention (Convention for the European Patent for the Common Market)

CPI	Código de Propriedade Industrial (Brazilian Law N. 5.772, of 21 December 1971- Industrial Property Code)
CPVO	Community Plant Variety Office
CPVR Regulation	Regulation N. 2.100/94, of 27 July 1994 on Community plant variety rights
CPVR	Community Plant Variety Right
Doc.	Document
EC Treaty	Treaty Establishing the European Community
EC	European Community
ECJ	European Court of Justice
ECL Rev.	European Competition Law Review
ECLA	United Nations Economic Commission for Latin America
ECR	European Court Reports
EEC	European Economic Community
EIPR	European Intellectual Property Review
EL Rev.	European Law Review
EPC	European Patent Convention (Convention on the Grant of European Patents)
EPO	European Patent Office
EPOR	European Patent Office Reports
ESCF	Economic-Social and Consultative Forum (MERCOSUL)
EU	European Union
Final Act	Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations
FTAA	Free Trade Area of the Americas
GATT	General Agreement on Tariffs and Trade
GMOs	Genetically Modified Organisms
IDB	Inter-American Development Bank

IIC	International Review of Industrial Property and Copyright Law
ILM	International Legal Materials
INPI	Instituto Nacional da Propriedade Industrial (National Institute of Industrial Property)
IPRs	Intellectual Property Rights
JPC	Joint Parliamentary Commission (MERCOSUL)
JWT	Journal of World Trade
JWTL	Journal of World Trade Law
LAFTA	Latin American Free Trade Association
LAIA	Latin American Integration Association
LMOs	Living Modified Organisms
Maastricht Treaty	Treaty on European Union
MAS	MERCOSUL Administrative Secretariat
MERCOSUL	Common Market of the South
Ministerial Declaration	Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations
Montevideo Treaty	Treaty Establishing a Free Trade Area and Instituting the Latin American Free Trade Association
MTC	MERCOSUL Trade Commission
NAFTA	North American Free Trade Agreement
OAS	Organization of American States
OJ EPO	Official Journal of the European Patent Office
OJ	Official Journal of the European Communities
Ouro Preto Protocol	Additional Protocol to the Treaty of Asuncion on the Institutional Structure of the MERCOSUL
Para (s).	Paragraph (s)
Paris Convention	Paris Convention for the Protection of Industrial Property

Paris Union	Paris Union for the Protection of Industrial Property
PCT	Patent Cooperation Treaty
PIC	Prior Informed Consent
PLT I Conf. Rec.	Records of the Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as far as patents are concerned - Volume I: First Part of the Diplomatic Conference
PLT	Patent Law Treaty (Basic Proposal for a Treaty Supplementing the Paris Convention for the Protection of Industrial Property as far as Patents are Concerned).
Proposed Biotechnology Directive (PBD)	Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions
Protocol of Brasilia	Protocol of Brasilia for the Settlement of Disputes
Rio Declaration	Rio Declaration on Environment and Development
SA	Summit of Americas
SNPRC	National Service for the Registration and Protection of Plant Varieties
SPC Regulation	Regulation N. 1768, of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products
SPC	Supplementary Protection Certificate
Treaty of Asuncion	Treaty Establishing a Common Market between the Argentine Republic, the Federative Republic of Brazil, the Republic of Paraguay and the Eastern Republic of Uruguay
Treaty of Montevideo 1980	Treaty for the Creation of the Latin American Integration Association
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRRs	Traditional Resource Rights
UN	United Nations

UNCED	United Nations Conference on Environment and Development
UNCHE	United Nations Conference on the Human Environment
UNEP	United Nations Environment Programme
UPOV Convention	International Convention for the Protection of New Varieties of Plants
Uruguay Round	Uruguay Round of Multilateral Trade Negotiations
US	United States of America
WIPO	World Intellectual Property Organization
WIPO Convention	Convention Establishing the World Intellectual Property Organization
WIPO Proposal	Propuesta de Disposiciones Legales en Materia de Invenciones y Diseños Industriales (Documento preparado por la Oficina Internacional de la OMPI a solicitud de la Comisión de Propiedad Intelectual del MERCOSUR)
WTO	World Trade Organization
WTO Agreement	Agreement Establishing the World Trade Organization
YEL	Yearbook of European Law
1991 UPOV Conference Records	Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants

INTRODUCTION

On 26 March 1991 the integration process for approximating the markets of the four countries of the Southern Cone of Latin America was put into practice through the signature of the Treaty of Asuncion by Argentina, Brazil, Paraguay and Uruguay. This has proved to be the most prominent integrating initiative among developing countries.

Alongside contemporary discussion about integrating projects, intellectual property protection has also been of great concern to developing economies. The world has grown smaller, facilitated by the development of technologies. It seems that boundaries in the modern world are no longer a geographic issue, but rather a political matter. It is of little doubt that development in science and technology strategies will play a determinant part for economic development in the next century and beyond. Intellectual property protection is necessarily the legal instrument which provides science and technology policies with a starting point.

It is worth considering that the market and creativity are the essential tools for development in the future. The competitiveness of nations and of industries are very much based on the continuous capacity for innovation. New technologies, therefore, are going to be used as a mechanism for economic development. Whether or not the benefits are going to be shared between the rich and poor part of developing countries is a matter for a broader political and economic analysis. The advance of technology may, nevertheless, play a determinant role in helping to eliminate social inequalities, as a result of economic development and of a more just social distribution of the profits and benefits which arise from science and technology development.

Patent protection should be analysed in the light of industrial and international trade policies. But a modern legal framework for patent protection must also consider the needs of industries and of society.

This research aims at analysing the present agenda of discussion in the Common Market of the South (MERCOSUL), taking into account the setting up of legal mechanisms for patent protection. It is therefore necessary to consider the developments in the national, supranational and international arena for assessing common measures which may be used by the integrating project of the MERCOSUL. Other issues have also raised concerns related to the protection and sustainable use of the environment and of natural resources. This research also studies the problems arising from actions on biological diversity prospecting, and its influence on the establishment of common legal developments in the field of patents for the MERCOSUL and for Brazil.

This thesis is introduced by Chapters 1 and 2.

Chapter 1 serves as a historical overview of the process of commercial, economic and political integration in Latin America. It initially describes the experience of the Latin American Free Trade Association (LAFTA), its failure, and its replacement in 1980 by the Latin American Integration Association (LAIA). It outlines briefly the setting up of the North American Free Trade Agreement (NAFTA) and the initiative towards a free trade zone for the Western Hemisphere. Chapter 1 also considers the necessary background to the integration process of the MERCOSUL, from the signature of the Treaty of Asuncion to the agreement on the Ouro Preto Protocol. In Section 2, Chapter 1 analyses the most recent historical origins of the Treaty of Asuncion, as well as its goals and the provisional institutional framework therein established. Moving further, a more definite institutional

mechanism is provided by the Ouro Preto Protocol and will be described as such. Lastly, relevant goals and initiatives towards broader economic and technical co-operation will be briefly considered in the context of the integration process of the MERCOSUL.

Chapter 2 outlines the establishment of an international system for patent protection. It begins by analysing the setting up of the Paris Convention, taking into consideration its institutional background and the principles which have given stronger reasons for the operation of this international arrangement. It also considers the efforts towards a multilateral organisation to administer and support the international harmonisation of intellectual property. Additionally, Section 1 of Chapter 2 analyses the setting up of an international system for co-operation in the field of patent granting procedures and the attempts to create a more advanced set of rules for harmonising patent protection on a world-wide basis.

With the intention of establishing a link between the liberalisation of international trade and intellectual property, Section 2 takes also into account the existing provisions of General Agreement on Tariffs and Trade (GATT) and its relationship with intellectual property rights (IPRs). Further, it studies the attempt of the United States of America (US), during the Tokyo Round of Multilateral Trade Negotiations, to create more effective rules against the commercialisation of counterfeit goods. Finally, Section 2 describes, in general words, the structure and main provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), as a result of the conclusion of the Uruguay Round of Multilateral Trade Negotiations (Uruguay Round).

There is no doubt that the European experience is of great relevance for the MERCOSUL. Chapters 3 and 4 consider the sophisticated legal and juridical structure

of the European Union (EU) to provide a basis for the discussion that will arise from the integration process of the MERCOSUL.

Chapter 3 intends to provide a view of the European Community (EC) experience on the establishment of rules and legal principles to regulate the exercise of patent rights. This Chapter is aided by the juridical approach that the European Court of Justice has taken towards the resolution of conflicts in relation with the exercise of patent rights, which apparently conflicts with the establishment of an area where goods circulate freely and where a healthy competitive market prevails. The administrative and legislative initiatives of the Commission of the European Communities are also considered.

Chapter 4, on the other hand, aims at analysing the attempts to establish a common and harmonised system for the protection of patents within the European Community. As a matter of institutional links, the practice and laws of the European Patent Convention (EPC) will be used as a very important reference for this purpose.

Chapters 5 and 6 propose a comparative analysis between international agreements, Brazilian nationals laws and regulations and the current stage of negotiations in the MERCOSUL.

Chapter 5 contemplates a more detailed discussion on the issues of patentability, considering the legal measures which must be studied when attempting to harmonise the issues on substantive patent law in the MERCOSUL. Part 1 addresses introductory issues of patentability such as the basic requirements for patent protection, exclusions and exceptions of patentability, rights conferred upon a patent, compulsory licensing and the term of protection for patents. Part 2 approaches the issues on the patentability/protectability of pharmaceutical products and processes, biotechnology and plant varieties.

Chapter 6 discusses two other relevant issues in relation to the exercise of patent rights in an integrated market. Complementing the discussion carried out by Chapter 3, this Chapter considers the principles of free movement of goods and the maintenance of a healthy competitive market, through the enforcement of competition regulations, as a means of assessing issues more closely related to economic integration, patent rights and the functioning of an integrated area.

A complementary Chapter has been included to discuss modern issues on IPRs and environmental conservation. The links between sustainable development, environmental protection and IPRs have been formally established by the Convention on Biological Diversity (CBD), as a result of the conclusion of the United Nations Conference on Environment and Development (UNCED). The CBD has dealt with the issues of intellectual property protection and biodiversity conservation paying particular attention to the development of new technologies and the role of developing countries in the context of this discussion.

Chapter 7 proposes to analyse the issues on the protection of biological diversity in broad terms. It examines the principles established by the CBD on access to genetic resources, intellectual property rights and transfer of technology. Additionally, it considers the modern approach towards the traditional practices and knowledge of local and indigenous communities as a tool for biodiversity conservation. Indigenous and local communities have also a very detailed knowledge about the components, properties and functions of biological diversity. National and international laws must, as a matter of fact, determine legal instruments to be used in this connection.

All the issues proposed are of great complexity. Each Chapter, if not each Section or Sub-section, may be considered as the subject of a Ph.D. thesis on its own. The present research may thus appear superficial and descriptive in its entirety. The analysis that follows intends to be a non-exhaustive view of most of the issues which may be considered by the integrating process of the MERCOSUL. Other complex issues, such as enforcement and dispute settlement procedures, have been considered even more perfunctorily. The present research intends, nevertheless, to provide general guidelines for future negotiations of the MERCOSUL in matters of technical and political complexities.

Following what has been said in the foregoing paragraph, it will be noted that parts of the present research are very detailed in describing the European legal and juridical experience. However, the thesis has not analysed in detail the same issues in the context of the MERCOSUL. Nor there is an in-depth discussion of the relevance of the particularities of the European experience for the integration process of the MERCOSUL. This methodology is based on two reasons:

(a) Limitation of space. The thesis already exceeded 100,000 words, which is the limit determined by Regulation 3.2.4. (c) (The University of Edinburgh, Postgraduate Study Programme). A detailed analysis of all the issues which are of relevance for the integration process of the MERCOSUL would make the present research too long. Although the thesis describes in detail the specific provisions of European and Brazilian legal framework, this is done only with a view to identifying general policy-making strategies which have to be considered by the integration process of the MERCOSUL. It is not an aim of this work to propose a model law for the protection of patents in the MERCOSUL.

(b) Lack of details in the negotiations of the MERCOSUL. The negotiating documents of the MERCOSUL are vague and do not reveal the detailed intentions of its States Parties. It is clear that the lack of technological capabilities of the States Parties of the MERCOSUL is a very important issue to be considered. Therefore, this thesis aims to provide the negotiations towards a Common Market of the South with a detailed view of the important concepts that have been developed and implemented in Europe - the Member States of which are far more capable technologically than the MERCOSUL - and to conclude with proposals of legislative and institutional strategies for determining not only a harmonised way to deal with patent protection, but also for establishing a minimum degree of science and technology development for the region. The examination of the details of European and Brazilian law provides an overview of the methods currently employed in these legal systems which are faced with their own particular problems of patent protection. This will hopefully inform the harmonisation process of the MERCOSUL about how to deal with such problems if and when the appropriate time comes. Presently, however, this thesis is concerned solely with determining broad guidelines to assist the MERCOSUL harmonisation process at its current state of development.

My presence in the United Kingdom, and later in Japan, has been of great significance in the attainment of the proposed task. It has, nevertheless, limited the opportunities of updating very important points. In Scotland I firstly benefited from the intellectual and physical infra-structure of the Faculty of Law of the University of Edinburgh, but, on the other hand, I had great difficulties to keep updating the

developments in Brazil and in the MERCOSUL, in spite of the kind help provided by so many individuals and institutions. The fellowship of the Institute of Advanced Studies of the United Nations University, in Japan, has also given me essential support to broaden my mind by providing me with close contact with the Japanese academic community and to further the environmental-related aspects of my research. It has, nevertheless, created difficulties to update the European part of the research. In general, however, I must say that both the British and Japanese experiences have been extremely advantageous.

The cross-references made throughout the present research, in relation to other parts of the thesis, should be understood in accordance with the following terminology:

- **Chapters** are named as such (Example: "Chapter 1 - Commercial Integration in Latin America");
- **Sections** are represented by one number (Example: "1. Historical Overview of Latin American Integration");
- **Sub-sections** are represented by two numbers (Example: "1.1. The Latin American Free Trade Association - LAFTA");
- **Paragraphs** are represented by three numbers (Example: "2.3.2. Towards broader international co-operation"). When the thesis refers to **paragraphs**, without initiating with a capital letter, it should be understood as paragraphs in a grammatical sense. And
- **Sub-paragraphs** are represented by one letter (Example: "(a) Open exclusive licence and absolute territorial protection").

All the translations from the Portuguese and from the Spanish languages are my own if not otherwise stated. The law is stated as at June 1995, based on my last field research trip to Brazil. I have, nevertheless, tried to update all the legal materials which were available until June 1996.

CHAPTER 1
COMMERCIAL INTEGRATION IN LATIN AMERICA

INTRODUCTION

When one thinks about commercial or economic integration, the first example which comes to mind is the integration process which has been carried out in Western Europe. It is true that this is the first modern integrating process which has had a successful outcome. It is worth noting, however, that this trend has spread all over the globe, including regions with different economic characteristics. Such initiatives may be found in Asia, in Africa and in the Americas.[1]

The present study intends to examine particularly one characteristic of Latin American integration which is currently happening in the southern cone of South America. The subject of this research, the integrating process of the envisaged Common Market of the South (MERCOSUL), is unavoidably related with the process of Latin American integration as a whole and which has been happening for at least the last fifty years.

This Chapter introduces the subject providing a historical overview on the integration processes and trends in Latin America. Initially, it gives an outline of the attempts of hemispheric integration. As a complementary issue, it also looks at the process of integration in the context of the North American Free Trade Agreement

---

[1]Historically speaking, it is assumed that the first customs union is the "Zollverein", which was formed in 1834 under the leadership of Prussia and which later defined the way for the unification of Germany. See, for this information, **Mario I. Blejer**, Economic Integration: An Analytical Overview, in **Inter-American Development Bank (IDB) & Institute for Latin American Integration (INTAL)**, Economic and Social Progress in Latin America: Economic Integration (1984 Report), Washington, DC: Inter-American Development Bank (1984), p. 5; and **José Artur Denot Medeiros**, MERCOSUL: Quadro Normativo e Institucional Pós-Outro Preto, [1995] 16 *BILA*, in *http://www.mre.gov.br/getec/webgetec/bila/16/artigos/1denot.htm*. It is possible to argue, however, that other examples - such as the establishment of the United States of America (US) or the

(NAFTA) and current attempts to establish a free trade zone in the Americas with continental dimensions.

Finally, it analyses in more detail the substantive aspects of the integration process which is happening in the MERCOSUL. Section 2 will, then, consider the origins of the MERCOSUL, moving further to the analysis of the basic institutional structure set up by the Treaty of Asuncion and of a more definite institutional framework which has been established by the Ouro Preto Protocol. It will also analyse briefly the aspects of broadening the scope of trade between the MERCOSUL and third countries or regions.

1. HISTORICAL OVERVIEW OF LATIN AMERICAN INTEGRATION

Before 1938 several programmes designed to establish a Latin American customs union or a free trade area had been initiated, but without further practical results. Later, in 1939 negotiations between Argentina and Brazil had taken place towards some co-operation in the area of industrial development, envisaging the setting up of a free trade regional commitment. Then, in 1940 an agreement was drafted to create the Inter-American Bank which, *inter alia*, would have the functions of controlling and operating payment compensation transactions[2]. Later, in February 1941, government representatives of the countries that have in their territories the River Plate, gathered together under the initiative of Argentina in the city of Rivera, in Uruguay, aiming at

---

integration of England and Wales, Ireland and Scotland by the Acts of the Union - may also be considered commecial, economic and political approximation.

[2]Eventually, the Inter-American Development Bank (IDB) was created in 1959 with the task of helping economic and social development in Latin America. The IDB has forty six members and headquarters in Washington, DC. The bank's fund derives essentially from contributions from its members; borrowing on the world's capital markets; the sale of participation in loans from the Bank's portfolio; special funds placed under the bank's administration; and loan repayments (in **Foreign & Commonwealth Office**, Latin America's Regional Integration Process, published in the Internet: *http://www.fco.gov.uk/reference/briefs/latinamerica.html*).

the creation of a regional block. In November 1941 the Argentinian and the Brazilian Ministers of Foreign Affairs signed, in Buenos Aires, an agreement in which both countries expressed their will to create a common customs regime with the purpose of establishing a "River Plate Customs Union". In addition to that, several bilateral agreements were drawn up towards the creation of a free trade area, or the establishment of a system of co-operation in the field of trade and payments, including Argentina, the Dominican Republic, El Salvador, Guatemala and Haiti.[3]

None of these agreements had concrete results, however, and the promising agreement between Argentina and Brazil, to create the "River Plate Customs Union", was definitely forgotten as a consequence of the Japanese attack on Pearl Harbor, when Brazil took a position in favour of the allied forces and of the United States, while Argentina preferred to keep a neutral position. This was the final element which made the working of this agreement impossible.[4]

As pointed out by Urquidi[5], however, the idea of a common market for Latin America has not been thought of in more practical terms until in its first session the Economic Commission for Latin America (ECLA)[6] approved "... a resolution (on June 24, 1948) which spoke of a 'Latin American Customs Union' as a possible

---

[3] See, *e.g.*, **Paulo Roberto de Almeida**, O MERCOSUL no Contexto Regional e Internacional, São Paulo: Edições Aduaneiras Ltda. (1993), pp. 73-74; *ibid.*, Cronologia da Integração Latino-Americana no Contexto do Sistema Econômico Internacional, [1995] 16 *BILA*, in *http://www.mre.gov.br/getec/webgetec/bila/16/4notas/1nota.html*; and **Victor L. Urquidi**, Free Trade and Economic Integration in Latin America: The Evolution of a Common Market Policy, Berkeley and Los Angeles: University of California Press (1968) 4th printing, pp. 20-22 and Appendix A.

[4] **Paulo Roberto de Almeida**, note 3, *supra*, p. 74.

[5] *Supra*, note 3, p. 47.

[6] The ECLA was founded by Resolution 106 (VI) of the Economic and Social Council of the UN (ECOSOC), on 5 March 1948, and was renamed Economic Commission for Latin America and the Caribbean (ECLAC), by Resolution 1984/67 of the ECOSOC, on 27 July 1984 (**Rüdiger Wolfrum & Christiane Philipp** (ed.), United Nations: Law, Policies and Practice, London: Martinus Nijhoff Publishers (1995), V. I, p. 434). To be coherent with the facts described throughout this Chapter, only the acronym ECLA will be used. Current members of the ECLA are all North, Central and South American and Caribbean States, as well as France, the United Kingdom, the Netherlands and Spain (*Ibid.*, pp. 444-445).

subject for discussion, ...". After that the ECLA has taken a more careful approach in addressing the issues of integration *per se*, preferring to discuss the matter of economic development and growth in Latin America as a whole. It must not be forgotten, nevertheless, that the theory of regional integration in Latin America has been essentially designed by ECLA, which had considered from the very beginning regional integration as a possible mechanism to be used for economic development[7]. Further studies were carried out by ECLA from 1954 to 1959 on the setting up of closer co-operation systems between the countries of Latin America.

It is important to note, in this regard, that the ideas put forward by ECLA at that time received great support from two distinct but complementary facts. Firstly, the countries of Central America, which had been negotiating bilateral free trade agreements since 1951, asked the ECLA Secretariat to carry out further studies on a broader integration system for those countries. As a result of these studies, between 1958 and 1961 several agreements have been adopted for the establishment of a Central American Common Market and its institutional framework[8].

Another fact that gave great support for ECLA's theories on Latin American integration, as a mechanism for continental economic development and industrialisation, was that Argentina, Brazil, Chile and Uruguay were already, in the

---

[7]For further discussion on the establishment of a theory for economic integration in Latin America by ECLA, see **Roger D. Hansen**. Central America: Regional Integration and Economic Development. Washington, DC: National Planning Association (1967). pp. 17-24.

[8]The Multilateral Treaty of Free Trade and Central American Economic Integration was signed in Tegucigalpa, Honduras, on 10 June 1958, by Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua (published in **Inter-American Institute of International Legal Studies**. Instruments Relating to the Economic Integration of Latin America. New York: Oceana Publications, Inc. (1968). pp. 3-14). The negotiations of this treaty were backed up by the technical advice of ECLA. In addition, the Caribbean States decided also to create an integrated area when, in 1965 Antigua, Barbados and Guyana signed the Treaty of Dickenson Bay establishing the Caribbean Free Trade Association (CARIFTA). Following the accessions of other Caribbean countries to the treaty and other attempts of integration in the region, thirteen countries (Antigua, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Jamaica, Montserrat, St. Kitts-Nevis-Anguilla, St. Lucia, St. Vicent, and Trindad and Tobago) signed the Treaty of Chaguaramas, replacing CARIFTA with the

middle of the 1950s, negotiating multilateral mechanisms for the liberalisation of trade. In 1958, then, ECLA organised the First Consultative Meeting about Commercial Policies in the South of the Continent, which took place in Santiago with the participation of Argentina, Brazil, Chile and Uruguay. This meeting concluded further that the four southern countries would start, at the same time as the initiative of ECLA to set up a Latin American Common Market, the drafting of policies towards the liberalisation of trade among them. In 1959 a second meeting of that type was held in Santiago, Chile, and a project for a free trade zone was drafted. As a result of this second gathering, Bolivia, Paraguay and Peru decided to support and participate in this project.[9]

The two initiatives discussed above had a successful conclusion in the setting up of institutional and multilateral mechanisms for the liberalisation of trade. The first of them, *i.e.* the integration process in Central America, is beyond the scope of this research and will not be analysed further. The second will be studied in more detail in Sub-section 1.1, *infra*.

As may be seen from what has been said in the foregoing paragraphs, the integration of Latin American countries is not a new issue. Several reasons have traditionally given rise to deeper discussion on integration issues. Probably the two most important of them have been, firstly, the need to foster industrialisation of the countries of the continent and secondly, another major concern of Latin American countries, has been the successful attempt by some European countries to establish a free trade zone as a first stage of the setting up of a fully operational Common Market, as a result of the signature of the Treaty of Rome in 1957. As a result of

---

Caribbean Community and the Caribbean Common Market (CARICOM). See, *e.g.*, **IDB & INTAL**, note 1, *supra*, pp. 38-47.

[9] **Paulo Roberto de Almeida**, note 3, *supra*, pp. 63-64.

these two major worries, Latin American countries have thought that integration mechanisms could provide the necessary means for strengthening trade among the possible participants, which, as a consequence, could make easier the process of planning the industrial development of the continent and, therefore, make their position stronger in world trade. Obviously, these are only a few of the reasons that have been predominant in the debate on Latin American integration. There are several others which are as important as these, such as the setting up of development policies that could help them to solve their foreign debt problems and the correction of trade balance payment situations. They are, nevertheless, all linked together and an economic analysis would necessarily have to take into account all of them. As the present research intends to analyse the legal aspects of commercial and economic integration, and the current Chapter intends to work rather as a historical and introductory overview of the process, economic issues will be avoided.

1.1. The Latin American Free Trade Association - LAFTA

After all the consultations and diplomatic negotiations which took place during the late the 1950s, the Treaty Establishing a Free Trade Area and Instituting the Latin American Free Trade Association (the Montevideo Treaty) was signed in Montevideo, Uruguay, on 18 February 1960[10], by Argentina, Brazil, Chile, Mexico,

[10]As published, with respective Protocols, in **Inter-American Institute of International Legal Studies**, note 8, *supra*. When the acronym LAFTA is used throughout this Chapter, or wherever, it means the Latin American Free Trade Association. The LAFTA had its headquarters in Montevideo, Uruguay. When the term "Area" is used in the text of the treaty it means the combined territories of the Contracting Parties (Montevideo Treaty, Art. 1). LAFTA had a complete juridical personality, empowered to do things such as sign contracts, acquire and dispose of the movable and immovable property it needs for the achievement of its objectives, institute legal proceedings and hold funds in any currency and transfer them when necessary (Montevideo Treaty, Art. 46).

Paraguay, Peru, and Uruguay.[11] In 1966 Venezuela joined LAFTA, and in 1967 Bolivia[12].

Venezuela decided not to accede to the agreement in the first place, because of the specific characteristics of its economy at that time. The government of Venezuela has seen the accession to the Montevideo Treaty as an opportunity for accelerating its economic development, on the one hand. On the other, it was aware that, as a country of high costs, Venezuela would be placed in a situation of disadvantage compared with the other signatory States. This explanation may be found in the fact that Venezuela had high industrial wages because its essential industrial activity was petroleum and iron ore sectors, which could pay relatively high wages that influenced the wage levels of other sectors of its national economy[13].

Colombia, on the other hand, was granted a moratorium until 18 June 1960 to accede to the Montevideo Treaty as a signatory State. This moratorium period was subsequently extended, but by the time the Montevideo Treaty came into force on 1 June 1961, Bolivia had not yet adhered to the Treaty, doing so only in 1967[14].

It is also necessary to mention that the government of Cuba expressed its intention to accede to the Montevideo Treaty in 1962. The Contracting Parties therefore convened to discuss the matter. It was decided that Cuba could not join the free trade arrangement because its economic regime was absolutely incompatible with the liberalisation process designed by the Montevideo Treaty. There were no further details on a precise definition of the incompatibility, in so far as Cuba had agreed to

---

[11]The signatory governments deposited their instrument of ratification on 2 May 1961 and the Treaty came into force thirty days later, by virtue of Article 57. Colombia deposited the instrument of accession on 30 September 1961, and Ecuador on 3 November 1961 (**Sidney Dell**, A Latin American Common Market?, London, New York, and Toronto: Oxford University Press and the Royal Institute of International Affairs (1966), p. 36).

[12]**IDB & INTAL**, note 1, *supra*, p. 43.

[13]**Sidney Dell**, note 11, *supra*, p. 47-49.

follow the liberalisation programme administered by LAFTA[15]. Though some authors claim that the judgement of the Contracting Parties was merely technical or economic[16], it is possible to find a political justification for this decision. Cuba was the only Latin American country which was clearly following a socialist economic approach, while at that moment all Latin American countries were in the position of becoming right-wing military regimes.

The Montevideo Treaty defined the institutional framework of the Latin American Free Trade Association and the legal mechanisms for the establishment and functioning of the Latin American Free Trade Area. Though this multilateral arrangement may be seen as a result of the four southern countries of South America (Argentina, Brazil, Chile and Uruguay) initiative, there is no mention of that in its text.

In its Preamble, the Montevideo Treaty lists the main objectives and goals to be reached by the integrating process established so far. Essentially, the signatory countries aim at eliminating barriers to intra-regional trade as a means of accelerating the economic development process of the participating countries (thus, ensuring "... a higher level of living for their peoples, ..."), and of strengthening national economies with the purpose of contributing "...to the expansion of trade within Latin America and with the rest of the world, ...". In addition to that, the Montevideo Treaty had as its main objectives the establishment, gradually and progressively, of a Latin American Common Market[17].

---

[14]**Victor L. Urquidi**, note 3, *supra*, p. 73, footnote 11.
[15]**Sidney Dell**, note 11, *supra*, pp. 46-47.
[16]*Ibid.*
[17]Montevideo Treaty, Preamble and Art. 54. It is important to note, however, that while the Preamble suggests that the participating countries should collaborate with each other for the purpose of attaining higher degree of integration, Article 54 appears to be a more practical and institutional mechanism for reaching the stage of a Latin American Common Market, when says: "To that end,

The trade liberalisation programme should be made fully operational within twelve years of the entry into force of the Montevideo Treaty[18]. During this time, the participating countries agreed to eliminate, gradually, all barriers "... in respect of ... all their reciprocal trade, such duties, charges, and restrictions as may be applied to import of goods originating in the territory of any contracting Party"[19]. The mechanisms which have been established by the Montevideo Treaty will be further discussed after a brief look at the institutional framework designed for the operation of the free trade area.

Before that, it is important to mention that the liberalisation of trade, as provided by the Montevideo Treaty was based on the principle of Most-Favoured-Nation Treatment, just as provided by the General Agreement on Tariffs and Trade (GATT), Article I. Article 18, Montevideo Treaty, had thus stated that,

> Any advantage, benefit, franchise, immunity or privilege applied by a contracting Party in respect of a product originating in or intended for consignment to any other country shall be immediately and unconditionally extended to the similar product originating in or intended for consignment to the territory of the other contracting Parties.

The principle of National Treatment should equally apply. Therefore, any duties or charges affecting products originating in the territory of a particular country of the Area, should enjoy treatment no less favourable than that accorded to similar national products.[20]

---

the [Standing Executive] Committee [of LAFTA] shall undertake studies and consider projects and plans designed to achieve this purpose, and shall endeavor to coordinate its work with that of other international organizations".

[18] *Ibid.*, Art. 2.

[19] *Ibid.*, Art. 3. This Article further defines the term "duties and charges" as "... customs duties and any other charges of equivalent effect - whether fiscal, monetary or exchange - that are levied on imports", excluding charges in respect of services rendered.

[20] *Ibid.*, Art. 21.

The institutional framework of the Montevideo Treaty created, in a first moment, two organs. The Conference of the Contracting Parties (the Conference) and the Standing Executive Committee (the Committee)[21]. Only after almost five years from its entry into force, Contracting Parties found out that the institutional structure designed for the functioning of the Latin American Free Trade Area needed to be enhanced and decided to create a Council of Ministers of Foreign Affairs (the Council) which should "... meet periodically to take decisions relating to the higher political conduct of affairs of the [Latin American Free Trade] Association"[22].

Then, in this first institutional period the Conference stands as the supreme organ of LAFTA and should adopt decisions in matters which required joint actions from the Contracting Parties, being empowered, *inter alia*, to take steps necessary for the effective functioning of the Montevideo Treaty; to carry out studies on the results of its implementation; to promote the negotiations of the National and Common Schedules; and to deal with business of common interest for the LAFTA[23]. The Conference, which would hold at least a regular session once a year[24], was composed of one representative of each Contracting Party who had one vote each[25]. The decisions of the Conference would be taken only with the presence of at least two-thirds of the Contracting Parties[26] and, during the first two years of the entry into force of the Montevideo Treaty, decisions should be adopted only when two-thirds of

---

[21]*Ibid.*, Art. 33.
[22]Resolution 117 (V), adopted at the Fifth Regular Session of the Conference of the Contracting Parties, on 30 December 1965.
[23]Montevideo Treaty, Art. 34.
[24]*Ibid.*, Art. 36.
[25]*Ibid.*, Art. 35.
[26]*Ibid.*, Art. 37.

the votes were affirmative and no negative vote was cast. This quorum of decision was also required for determining the voting system after the two-year period[27].

The Committee was the permanent executive organ of the Association with the functions of supervising the implementation of the provisions of the Montevideo Treaty, which included, *inter alia*, the duty to convene the Conference; to represent the Association in dealing with third countries and international organs; to undertake studies, to suggest measures and to submit recommendations to the Conference; to submit to the Conference at its annual regular session a report on its activities and on the results of the implementation of the Montevideo Treaty; and, obviously, to undertake any work assigned to it by the Conference[28]. The Committee was composed of one representative of each Contracting Party, who had a single vote and who was required to have an alternate representative[29].

It is also interesting to note that a specific provision provided for the possibility of the Committee to request, for the organs of the Association, the technical advice of the ECLA and of the Inter-American Economic and Social Council of the Organization of the American States (OAS)[30]. This is a possible recognition of the technical advice that has been successfully carried out by the ECLA to lead, draft and establish the outline of LAFTA.

The Committee had a Secretariat, headed by an Executive Secretary, and administrative personnel. The Executive Secretary was elected by the Conference for

---

[27] *Ibid.*, Art. 38.
[28] *Ibid.*, Art. 39.
[29] *Ibid.*, Art. 40.
[30] *Ibid.*, Art. 44. The OAS, with headquarters in Washington, DC, is the successor of several other Pan-American organisations which were created in the nineteenth and early twentieth centuries. The OAS was given permanent legal and institutional structure with the signature of the Charter of Bogota, in April 1948. Eventually, the Charter of Bogota came into force in December 1951. The OAS has the goals of helping to guarantee peace and security in the continent; resolve political, judicial and economic problems between its members; promote mutual understanding on

a three-year term and was eligible for re-election, and would be allowed to attend and carry out the secretary duties of the plenary meetings of the Conference without the right to vote.[31] Neither the Executive Secretary nor the administrative personnel of the Secretariat were allowed to seek or to receive instruction from any government or any national or international entity[32].

Later, on 12 December 1966, Articles 33 to 39 of the Montevideo Treaty were amended by the Protocol Institutionalising the Council of Ministers of Foreign Affairs of the LAFTA[33]. Under this new institutional framework, the Council became the supreme organ of LAFTA with the duty of making the decisions concerning the conduction of its higher policy and empowered, *inter alia*, to enact general rules which would permit a better achievement of the objectives of the Montevideo Treaty; to examine the results of the tasks accomplished by LAFTA; to fix the basic rules governing the relations of LAFTA with third countries, regional associations and international organisations and entities; and to amend the Montevideo Treaty pursuant to Article 60.[34] Generally speaking, the Conference and the Committee were left with the same tasks as before, but under the supremacy of the Council. The LAFTA's institutional framework may be visualised more clearly in Chart 1, Appendix I, *infra*.

In relation to the voting system, it was determined that both the Council and the Conference could meet and take decisions only in the presence of at least two-

---

development; and provide common action in the event of aggression (in **Foreign & Commonwealth Office**, note 2, *supra*).

[31] *Ibid.*, Art. 41.

[32] *Ibid.*, Art. 42.

[33] Published in **Inter-American Institute of International Legal Studies**, note 8, *supra*, pp. 318-321.

[34] Montevideo Treaty, as amended by the Protocol Institutionalising the Council of Ministers of Foreign Affairs, Art. 33. The Council, by virtue of Article 33, was composed by the Ministers of Foreign Affairs of the Contracting Parties, unless such a duty was nationally assigned to another branch of the government of a Contracting Party.

thirds of the Contracting Parties[35]. The Council, however, was empowered by the amended Article 34 (g), Montevideo Treaty, to change its own system of voting and that of the Conference.

For the liberalisation of intra-regional trade, there are two mechanisms which were designed to be used for the negotiation of the removal of barriers among the Contracting Parties of LAFTA. They are the National Schedules and the Common Schedules.

In connection with the preparation of National Schedules[36], Contracting Parties were requested to grant "... to other contracting Parties reductions in duties and charges equivalent to not less than eight (8) per cent of the weighted average applicable to third countries" until the full elimination of customs duties or any other charge having equivalent effect[37]. These negotiations would be carried out yearly and the mechanism for the elimination of trade restrictions would come into force until the 1 January of each following year[38].

The negotiation of the National Schedules should follow the deadlines as described in the Protocol: firstly, before 30 June of each year, Contracting Parties should provide the Committee with a list of products which they were applying for concessions. Then, before 15 August of each year, Contracting Parties should provide the Standing Executive Committee with a list of items for which they were willing to grant concessions, but this second schedule would apply only to the subsequent years, not to the first year of entering into force of the Montevideo Treaty, when the

---

[35] *Ibid.*, Art. 37.
[36] According to Article 4 (a), Montevideo Treaty, the National Schedules consist of "... specifying the annual reductions in duties, charges and other restrictions which each contracting Party grants to the other contracting Parties ...".
[37] Montevideo Treaty, Art. 5.
[38] *Ibid.*, Art. 6.

corresponding final date should be 1 October[39]. Further, on 1 September of each year (with the exception of the first year, when the corresponding date should be 1 November) the Contracting Parties would initiate the negotiation of the concessions to be accorded by each to the others as a whole. These concessions would be assessed multilaterally, but would not preclude bilateral negotiation in connection with the interests attached to specific products[40]. After negotiations were concluded, the Committee would make the necessary calculations to assess the weighted average of duties and charges of individual concessions in force for imports from within the Area, in relation to the weighted average of duties and charges applicable in the case of third countries[41]. If such assessment concluded that the minimum commitment of eight per cent had not been reached so far, the negotiations would continue so that the list of reductions of duties and charges of each Contracting Party could be simultaneously published not later than 1 November of the negotiating year, that they could come into force from January of the following year[42].

It should be noted, moreover, that for the calculation of the "weighted averages" Contracting Parties would consider two mechanisms: "one corresponding to the average of the duties and charges in force for third countries; and the other to the average of the duties and charges which shall be applicable to imports within the Area"[43].

It is also important to mention that the Montevideo Treaty established that the application of the National Schedules mechanism should be based on the principle of

---

[39] *Ibid.*, Protocol N. 1, Title III (10).
[40] *Ibid.*, Title III (11).
[41] *Ibid.*, Title III (12).
[42] *Ibid.*, Title III (13).
[43] *Ibid.*, Title I (2).

reciprocity[44], which "... refers to the expected growth in the flow of trade between each contracting Party and the others as a whole, in the products included in the liberalization programme and those which may subsequently be added"[45].

The Common Schedules should be understood as a list of products for which Contracting Parties agree, collectively, to eliminate duties, charges and other restrictions completely and that, in terms of the aggregate value of the trade among the participating countries of the regional agreement, does not constitute less than (a) twenty five per cent during the first three-year period; (b) fifty per cent during the second three-year period; (c) seventy five per cent during the third three-year period; and (d) all of such trade during the fourth three-year period[46]. Once products were included in the Common Schedule the concessions granted were irrevocable[47].

For the negotiation of the Common Schedule, the following deadlines should have been taken into account: firstly, during each three-year period and not later than 31 May of the third, sixth, ninth and twelfth years from the date of entry into force of the Montevideo Treaty, the Standing Executive Committee would supply the Contracting Parties with statistical data relating with the value and volume of the products traded in the Area during the preceding three-year period. This data should be eventually used for indicating the proportion of aggregate value which each product individually represented[48]. In addition to that, before 30 June of the third, sixth, and ninth years from the date of entry into force of the Montevideo Treaty, the Contracting Parties had to exchange the lists of products whose inclusion in the

---

[44]Montevideo Treaty. Art. 10.
[45] *Ibid.*, Art. 13.
[46]*Ibid.*, Art. 7.
[47] *Ibid.*, Art. 8.
[48]Protocol N. 1. Title IV. (14).

Common Schedule they were willing to negotiate[49]. Then, the Contracting Parties would conduct negotiations to establish, before 30 November of the third, sixth, ninth and twelfth years, a Common Schedule including goods where the values meet the minimum commitments referred to in Article 7 of the Montevideo Treaty.

Some escape clauses could be used in specific situations. For instance, countries which would be in a position of disadvantage concerning the trade between one Contracting Party and the others as a whole, in relation to the products included in the programme for the liberalisation of trade, could request the Contracting Parties to "... consider steps to remedy these disadvantages with a view to the adoption of suitable, nonrestrictive measures designed to promote trade at the highest possible levels"[50]. If the circumstances referred to in Article 11 of the Montevideo Treaty persist, at the request of the affected Contracting Party, Contracting Parties should seek for further solutions and remedies to end such disadvantages[51].

Additionally, if the importation of products included in the liberalisation programme occurred in such quantities or conditions that they had, or were liable to have, serious repercussions on specific productive activities of vital importance to the national economy, Contracting Parties could, as a provisional measure, authorise the Contracting Party in question to impose non-discriminatory restrictions upon those imports[52]. The Montevideo Treaty also says that if measures have been authorised to a Contracting Party to correct an unfavourable overall balance of payments, these measures could have been extended, on a provisional basis, to intra-Area trade in the products included in the liberalisation programme[53]. If these measures required

---

[49] *Ibid.*, Title IV (15).
[50] Montevideo Treaty, Art. 11.
[51] *Ibid.*, Art. 12.
[52] *Ibid.*, Art. 23.
[53] *Ibid.*, Art. 24.

immediate actions from the affected Contracting Party, the latter could take the necessary actions as provided by Articles 23 and 24, but should inform the Committee immediately which measures have been taken[54].

The Montevideo Treaty has also adopted special provisions for the co-ordination of agricultural development and commodities trade policies, for the purpose of ensuring that normal supplies to the population would be guaranteed, also raising the standards of living of the rural population, without disorganising the regular productive activities of each Contracting Party.[55] Because of the specific features designed to protect the agricultural activities of the Contracting Parties of the Montevideo Treaty, GATT has requested information from Members of LAFTA in respect of whether priority would be given to imports of agricultural products originating in the territories of other LAFTA Members, even in the case of lower prices from third countries. The answer was that the granting of priority to LAFTA suppliers was dependent mainly on the competitiveness of the prices of the supplier against the price offered by third countries. This has raised questions in relation to the comparison with the treatment granted by the European Economic Community (EEC) to agricultural products. Though the latter was in a rather more stable economic situation, it did grant preferential treatment for agricultural products within the EEC. Additionally, it was thought that agricultural products could play a very determinant role in the context of LAFTA Members to promote the modernisation of the agricultural economy of the region.

Another important aspect of the Montevideo Treaty was its intention to promote industrial development, by reconciling the import and export regimes of the

---

[54] *Ibid.*, Art. 25.
[55] *Ibid.*, Arts. 27 to 31.

Contracting Parties and by co-ordinating the treatment accorded to capital, goods, and services from outside the Area[56]. This should have been done through the progressive promotion of closer co-ordination of their industrial policies and through the negotiation of mutual agreements on complementary economies by industrial sectors[57].

The situation of the less-developed economies has also been taken into consideration, and several measures were designed to create conditions to guarantee the growth of all economies of the Area.[58] Less-developed economies were then granted a preferential treatment in addition to that granted to all Contracting Parties. Less-developed countries could, therefore, reduce their import duties, charges and other restrictions at a slower pace than other Contracting Parties.

Aiming at giving other non-signatory countries of Latin America the support to join LAFTA, Contracting Parties have decided to be reasonably flexible in relation to future accession. Thus, other Latin American States which would like to accede to the LAFTA in the future would be required only to deposit the relevant instrument of accession with the government of Uruguay, and the Treaty would come into force for the acceding State thirty days after the deposit of the corresponding instrument of accession.[59]

---

[56] *Ibid.*, Art. 15.

[57] *Ibid.*, Arts. 16 (a) and (b), respectively. The Montevideo Treaty, however, does not specify the scope of such mutual agreements, which may lead one to think that the procedures employed would vary from case to case (**Sidney Dell**, note 11, *supra*, p. 42).

[58] *Ibid.*, Art. 32. It is noteworthy that Protocol N. 5 of the Montevideo Treaty recognised the situation of Bolivia and Paraguay, providing preferential treatment to them. Additionally, in its first session in July 1961 the Conference of the Contracting Parties approved the extension of preferential treatment to Ecuador, on joining LAFTA (**Sidney Dell**, note 11, *supra*, p. 42).

[59] *Ibid.*, Art. 58. On the other hand, according to Article 64, Montevideo Treaty, a country wishing to withdraw from the Treaty could do so informing the other Contracting Parties of its intention during a regular session of the Conference, and should formally submit the instrument of denunciation at the following regular session. The rights and obligations of the denouncing government in relation with reductions in duties and charges and other restrictions, received or granted under the liberalisation programme, would remain in force for a period of five years from the date which the

The LAFTA, actually, has been an agreement full of good intentions to promote the economic development of Latin America as a whole. Several problems have, nevertheless, been noticed from the very beginning as contributing to the failure of the integrating process.

Contracting Parties have, for instance, drafted provisions on the co-ordination of external policies, but have failed to adopt rules on the harmonisation of internal policies. It is possible to note that the LAFTA process has failed from the very beginning and not even the short term goal of setting up a free trade area in a twelve-year period was met.

At the beginning, the negotiations of National Schedules seemed to point to a successful process, in so far as during the first two rounds of negotiations the concessions were well above the eight per cent required by the Montevideo Treaty. This has actually highlighted the fact that the easiest concessions - usually those already part of the intra-regional trade and almost entirely based on traditional primary products - have been included in the negotiations. During the third and fourth round of negotiations the number of concessions was clearly reduced.

In addition, the rise of trade that followed the signature of the Montevideo Treaty was unevenly distributed. While Argentina supplied about one-third of LAFTA's intra-regional trade in 1961, and nearly half of it from 1961 to 1964, fifty per cent of the concessions during the first three rounds were made only by Argentina, Brazil and Ecuador[60]. The negotiations of the Common Schedules, on the other hand,

---

denunciation becomes formally effective. This would not apply if the denouncing government would consent to a shorter period.

[60]See, *e.g.*, **Sidney Dell**, note 11, *supra*, pp. 70-73.

appeared to be of no importance at all when one takes into account that "[o]nly one common list was approved in 1964 and never became effective"[61].

After 1969, the enactment of national lists was completely forgotten and the negotiations of LAFTA gave more emphasis to the agreements on industrial compatibility, rather than on trade issues as such. This was actually followed by the negotiations that had been carried out by the countries of the Andean region, which concluded a Sub-regional agreement, signed in Bogota on 26 May 1969 (known as the "Cartagena Agreement") by Bolivia, Colombia, Chile, Ecuador and Peru[62]. Venezuela adhered to the agreement as an original Member on 13 February 1973. Chile withdrew in 1976. In 1992, Peru suspended its participation in the tariff and other economic mechanisms[63]. The legislative functions of this integrated system are carried out by the Commission. Its decisions are applicable in the Member States without the need of further implementation by national law[64].

From 1969 to 1975, the Andean Pact actually saw a dynamic evolution of the sub-regional process of integration and a very active legislative process on the harmonisation of national legislation, and on the setting up of a programme on liberalisation of trade. The ambitious aims of the Andean Pact suffered from the economic crises that affected the whole of Latin America, and it was slowed down

---

[61] **IDB & INTAL**, note 1, *supra*, p. 17.

[62] The stagnation of the process and the sectoral contractions within LAFTA led several Contracting Parties, in particular those of the Andean region, to be convinced that a different type of integration project was required. This is essentially the main justification for the creation of the Andean Pact, following a much more ambitious integrating project (**IDB & INTAL**, note 1, *supra*, p. 20).

[63] **S. Kendall, S. Bowne, J. Mann & S. Fidler**, Andean Pact Still Split on Outside Tariff, *Financial Times*, 12 May 1994, p. 6. It is worth noting that Peru did not withdraw from the agreement itself. Peru was temporarily allowed to waive some of its obligations. It was done within the framework of the Cartagena Agreement and with the express consent of the other Members.

[64] **S.C. Zalzuendo**, Patentes en el Grupo Andino: Reforma de 1991,[1991] 39 *Revista del Derecho Industrial* 457-465, at p. 459.

after the mid 1970s[65], when several integrating projects, such as the creation of a common external tariff, were not fully implemented[66].

Several economic justifications may be given for the failure of the LAFTA process, in addition to those just mentioned. It is argued that the lack of harmonisation of economic and monetary policies, the absence of common marketing strategies or of exploitation of common lines of credit, together with the deficiency of a common policy for foreign investments, are all additional reasons for the failure of LAFTA.[67] It is also necessary to point out, as Paulo Roberto de Almeida[68] has properly done, that another reason, based on political adjustments, may have played a vital role in this context. Paulo Roberto de Almeida recalls that after the second half of the 1960s, until the beginning of the 1980s, Latin American countries were under military dictatorships which, by their nature, expressed preferences for economic systems which were extremely closed to international markets, with strong tendencies to self-sufficiency and government predominance in the economy.

1.2. The Latin American Integration Association - LAIA

The first actual expression of the lack of success of the LAFTA process was briefly described above, *i.e.* the creation of the Andean Pact in 1969. In addition, Contracting Parties decided to create an agreement to replace LAFTA which did not seek to establish a free trade area in Latin America based on strict rules and ambitious

---

[65] **Paulo Roberto de Almeida**, note 3, *supra*, pp. 65-66.
[66] Eventually, the Andean Pact's common external tariff came into force on 1 January 1995.
[67] **IDB & INTAL**, note 1, *supra*, p. 19.
[68] **Paulo Roberto de Almeida**, note 3, *supra*, p. 65.

deadlines, but, instead, aimed at promoting the creation of bilateral commercial agreements that could include other countries of the continent in the long run[69].

Based on the principles of pluralism[70], convergence[71], flexibility[72], differential treatment[73], and multiplicity[74], three basic instruments have been created to promote the establishment of the Latin American Integration Association (LAIA) . Firstly, "regional tariff preferences"[75] which are limited to reductions in the external tariff granted reciprocally by the countries "... and which applied with reference to the tariff level in effect *vis-a-vis* third countries"[76]. This type of mechanism does not call for the creation of a common external tariff and is intended only to grant specific preferences to other members of LAIA.

The second mechanism is the "regional tariff arrangements"[77] in which all Members of LAIA are to participate[78], based on the same rules as the third mechanism for trade liberalisation, "partial tariff arrangements". The latter is a mechanism which

---

[69]The Treaty for the Creation of the Latin American Integration Association (Treaty of Montevideo 1980) was signed in Montevideo, Uruguay, on 12 August 1980, by Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Mexico, Paraguay, Peru, Uruguay and Venezuela, and came into force on 18 March 1981 (**Avelino de Jesus**, Relações Comerciais Internacionais: GATT, ALADI, MERCOSUL, SGP, SGPC, NCPD, São Paulo: Edições Aduaneiras (1992), p. 68). The Treaty of Montevideo 1980 is published in **Paulo Roberto de Almeida**, MERCOSUL: Legislação e Textos Básicos, Brasília: Senado Federal (1992), pp. 32-54.

[70]Which means that it shall be based on the political will of the Members States to integrate, beyond the political or economical diversity that might exist between them (Treaty of Montevideo 1980, Art. 3 (a)).

[71]Being the progressive multilateralisation of partial tariff arrangements, through periodical negotiations between the Members States (Treaty of Montevideo 1980, Art. 3 (b))

[72]Aiming at creating the capacity to permit further agreements on partial tariff arrangements (Treaty of Montevideo 1980, Art. 3 (c)).

[73]Making sure that in both the regional and partial tariff arrangements, it is recognised the economic differences among the participating countries (Treaty of Montevideo 1980, Art. 3 (d)).

[74]Being the creation of possibilities in relation to forms and adjustments between the Members States, using the existing instruments to make the regional markets more dynamic and broader (Treaty of Montevideo 1980, Art. 3 (e)).

[75]*Ibid.*, Art. 5.

[76]**IDB & INTAL**, note 1, *supra*, p. 51.

[77]Treaty of Montevideo 1980, Art. 6.

[78]It is worth noting that by virtue of Article 18, Treaty of Montevideo 1980, Members of LAIA are requested to approve a list of preferences for less-developed countries, to agree upon the total elimination of customs barriers, without reciprocity, for some specific products, aiming at creating

intends to create conditions to deepen the regional integration process, through progressive multilateralisation[79]. This mechanism shall be based on the following rules: (a) it shall be open to accession from other Members States; (b) it must contain clauses which lead to convergence, thus benefiting all Members States; (c) it shall contain clauses leading to convergence, as well as preferential treatment to less developed countries; (d) it must have a duration of at least one year; and (e) it may contain specific norms on safeguard measures, non-tariff restrictions, and others[80].

To sum up, the difference between LAFTA and LAIA, as integrating systems, is that the latter emphasised the setting up of partial preferential agreements in a bilateral basis - and there was no intention to establish a more formal type of regional commercial agreements on a multilateral basis - while the former's aim was to establish a programme of common commercial liberalisation, envisaging a customs union type of integration and a Common Market agreement in the future. It is important to mention, however, that the LAIA also has the main goal of a Latin American Common Market, as part of its major objectives, but using more flexible mechanisms than those established by LAFTA[81].

The LAIA was, however, brought to life in a very difficult time. Following the petroleum crisis, at the end of the 1970s, which considerably affected oil importing countries such as Brazil, Latin American countries faced a large economic problem derived from the foreign debt crisis in the early 1980s, which was made clear by the

---

favourable conditions for the participation of those countries in the economic development which will be taking place.

[79]Treaty of Montevideo 1980, Art. 7. These arrangements can be of any type (*Ibid.*, Art. 8), in so far as they take into account further issues such as science and technological co-operation, the promotion of tourism and the conservation of the environment (*Ibid.*, Art. 14).

[80]*Ibid.*, Art. 9.

[81]*Ibid.*, Art. 1.

Mexican moratorium.[82] The regional tariff arrangements of LAIA had, thus, no practical results and the intra-regional trade among the members of LAIA was greatly reduced after 1981.[83]

The Treaty of Montevideo of 1980 created, virtually, the same institutional structure as LAFTA with a few terminological differences. The highest organ of the Association is the Council of Ministers of Foreign Affairs, as in the LAFTA, and the LAFTA's Conference of the Contracting Parties was replaced by the Conference on Evaluation of Convergence. Finally, the Standing Executive Committee of LAFTA was changed by a Committee of Permanent Representatives, also helped by an administrative structure (the Secretariat) headed by a Secretary General.[84] In Chart 2, Appendix I, *infra*, a more comprehensive view of the institutional framework of the LAIA is presented.

The Treaty of Montevideo of 1980 did not deal in much detail with issues about regional co-operation in the fields of industrialisation or agriculture, but recognised and created mechanisms designed to help the less-developed countries. Essentially, the mechanisms created are the establishment of more favourable conditions for less-developed countries, based on the principles of non-reciprocity and community co-operation; the setting up of preferential treatment to benefit these countries; and the establishment of mechanisms to ensure that the preferential treatment granted to less-developed economies could eventually come into practical effect. To attain this goal, mechanisms for opening the markets for products from less-developed countries have been created, as well as Special Co-operation

---

[82]**Paulo Roberto de Almeida**, note 3, *supra*, p. 67.
[83]*Ibid.*
[84]Treaty of Montevideo 1980, Art. 28.

Programmes and an Office for Economic Promotion within the Executive Secretariat.[85]

It seems that LAIA has no practical importance, since it is very limited in scope, dealing chiefly with trade arrangements and, somehow, with the settlement of trade balances, explicitly lacking mechanisms for the co-ordination of internal and external economic policies. The intention of LAIA's Members was actually to provide the integration system with less strict liberalisation rules and deadlines. Following the tragic end of the LAFTA, Contracting Parties had also thought of a more flexible agreement which could keep the machinery of Latin American integration running, while giving time for the future to come. LAIA was designed upon a very pragmatic and practical basis, aiming at promoting free trade in the continent without determining how countries should do so, and without creating deadlines which would become difficult to meet, putting the whole process at risk. In fact, LAIA started to gain more importance in the trade context of Latin American integration from the late 1980s to the beginning of the 1990s. An example of the partial success of LAIA, in recent times, is that there are currently thirty two partial and other economic agreements in place, half of which have been signed in the 1990s[86].

1.3. From NAFTA to a Free Trade Area of the Americas (FTAA)?

To assess the background to the setting up of the North American Free Trade Agreement (NAFTA), one will have to consider firstly the geographical and economic conditions that have, naturally, been of great importance for making the links between Canada, Mexico and the United States of America (US). Initially, there are three

---

[85] *Ibid.*, Chapter III. See, for further details on the application of the goals and mechanisms to help less-developed economies, **IDB & INTAL**, note 1, *supra*, pp. 71-72.

events that have played a very determinant part in this context, and which should be mentioned[87].

In the first place, Mexico has been through a difficult economic and financial crisis since the beginning of the 1980s. This led the governments of President la Madrid and, subsequently, of President Salinas, to determine the boundaries of the development strategies, considering structural reforms and strict fiscal adjustments aiming at tackling the problems arising from the foreign debt crisis. These adjustments' objectives were to review Mexican's foreign trade policy which, in the government's view, would lead to an increase of the competitive capacity of its industries. Following that, Mexico acceded to the GATT in 1986. Several other actions have been taken in the field of liberalisation of trade, such as the fixing of a twenty per cent limit for import taxes which was fully implemented by 1988. These economic adjustments had very positive effects on the foreign practice of the country, substituting the external trade manner of exporting primarily oil and minerals, to the increasing exportation of other manufactured products. The liberalisation of external trade, as a strategy designed to initiate and further sustain economic development, has unavoidably made the economic environment of Mexico more attractive to US commerce and investments.

Secondly, a bilateral free trade agreement was negotiated, and implemented in January 1989 between the US and Canada with the inclusion of several mechanisms for the liberalisation of intra-bilateral trade, comprising the liberalisation of goods, services and investments, excluding intellectual property protection issues. The

---

[86]**Organisation of American States (OAS).** Toward Free Trade in the Americas. (1995). as downloaded from *http://www.oas.org/frtrade.htm*.

[87]Most of the information provided below about these three events which have led to the creation of the NAFTA has been generally extracted from **Ministério das Relações Exteriores (MRE) &**

integration of markets, and approximation of interests between both countries, was a long historical process, and the setting up of a formal liberalisation programme was merely part of the natural and geographical consequences of this process[88].

The third event is the launching, in 1990, by US President George Bush, of a programme called the "Enterprise for the Americas Initiative" which was a proposal for a new partnership between the US and Latin America, as part of a global strategy of the US to increase its commercial participation in the whole hemisphere. This initiative called for the expansion of US trade with Latin America; for the increase of the participation of the US private sector in the region; and for the negotiation of reduction of Latin American debts owed to the US government. The Enterprise for the Americas Initiative advocates that both Latin American countries and the US would strengthen their position in the world market[89]. This is probably a major starting point for modern discussion on a Free Trade Area of the Americas (FTAA), which will be further analysed later in this Sub-section.

Following the description of these historical facts, it is important to mention that bilateral negotiations between the US and Mexico - later joined by Canada - were taking place very effectively, and the consequence was an agreement on the creation of a tripartite liberalisation programme among the North American partners.

On 12 August 1992, Canada, Mexico and the US ended the negotiations of the North American Free Trade Agreement[90] with the intention to eliminate gradually

---

Fundação Centro de Estudos de Comércio Exterior (FUNCEX/RJ). O Brasil e o NAFTA: Impacto sobre Comércio e Investimentos. Brasília: ABIGRAF (1993). pp. 14-25

[88]Moreover, the 1965 deal on trade in auto and automotive parts between the Canada and US had not showed much effectiveness against the outgrowing trade between the two countries.

[89]**Foreign & Commonwealth Office**, note 2, *supra*.

[90]The negotiations towards the agreement on the NAFTA started on 12 June 1991, in Canada. The Agreement itself was signed on 17 December 1992 (supplemented in 1993 by the negotiation of "side agreements" in the areas of labor, the environment, and safeguards) and started to operate on 1 January 1994. According with Article 101, the NAFTA establishes a free trade area in accordance with Article XXIV of GATT.

the existing trade barriers to goods and services within the territories of the Parties; to promote conditions of fair competition; to increase investment; to protect and enforce IPRs; and to broaden the application of NAFTA through co-operation arrangements in a trilateral, regional or multilateral basis[91].

These goals will be achieved through the abolishment of restrictions on investments and services; through the creation of rules and restrictions on the liberalisation of some industrial sectors such as automotive, textile, energy, petrochemical, and agriculture; through the setting up of sanitary and phytosanitary measures; and through the regulation of telecommunications, competition and environmental policies, and intellectual property rights.

The elimination of tariff and non-tariff barriers to intra-NAFTA trade will be done gradually in a period of fifteen years. It is important to note, however, that the liberalisation programme of NAFTA may not be considered, in a strict sense, a free trade area arrangement, but rather a negotiating process which will abolish trade barriers on a limited basis, maintaining some non-tariff barriers such as domestic subsidies and agriculture quotas[92]. It is even possible to assume that the NAFTA is rather an agreement to abolish tariff restrictions to trade among the participating countries - a type of trilateral GATT - than an agreement which establishes a free trade zone as such.

The institutional structure of NAFTA is based on a Free Trade Commission, composed by Ministers of the Parties or their designees, and a Secretariat. The Free Trade Commission will have, among others, the following tasks: to supervise the implementation and further elaboration of NAFTA; to resolve disputes on the

---

[91]NAFTA. Art. 102 (1).
[92]**MRE & FUNCEX/RJ**. note 87. *supra*. p. 13.

interpretation or application of NAFTA's provisions; and to supervise the work of the Committees and Working Groups established by the agreement[93].[94] All the decisions of the Free Trade Commission must be taken by consensus, unless otherwise agreed[95]. The Free Trade Commission will convene at least once a year in regular session[96]. The Secretariat, which will be divided into national sections[97], has the duty to provide technical and administrative assistance to the Free Trade Commission and to the Panels, Committees and Working Groups[98].

Additionally, the link between the main goals of NAFTA, as an US strategy to broaden the latter's commercial influence in the continent, shall be briefly described. Between 9-11 December 1994, thirty four Heads of States of the Americas[99] gathered together in Miami to participate of the Summit of Americas (SA), and discussed further mechanisms for hemispheric co-operation. The outcome of the SA is a Declaration of Principles, entitled "Partnership for Development and Prosperity:

---

[93]NAFTA. Annex 2001.2 creates eight Committees - (a) trade in goods; (b) trade in worn clothing; (c) agricultural trade; (d) sanitary and phytosanitary measures; (e) standards-related measures (which is composed by 4 Sub-committees on land transportation standards, telecommunications standards, automotive standards and labelling of textile and apparel goods); (f) small business; (g) financial services; and (h) an Advisory Committee on Private Commercial Disputes -, and six Working Groups - (a) rules of origin; (b) agricultural subsidies; (c) two Bilateral Working Groups (Mexico - USA and Canada - Mexico); (d) trade and competition; and (e) temporary entry.

[94]*Ibid.*, Art. 2001 (1).

[95]*Ibid.*, Art. 2001 (4).

[96]*Ibid.*, Art. 2001 (5).

[97]*Ibid.*, Art. 2002 (1) and (2).

[98]*Ibid.*, Art. 2002 (3).

[99]With the exception of Fidel Castro from Cuba who was not invited. Note that, as it has been noted before in Sub-section 1.1 in relation to the decision against Cuba's adherence to the LAFTA, it was showed that the decision in the context of LAFTA had a political basis rather than a technical one, against the opinion of some authors. The justification of the host of the Summit of Americas, President of the US, Bill Clinton, for not inviting Cuba, is that the latter was the only country of the Americas where democracy did not prevail. For this information, see **White House**. Remarks by the President to Members of the Summit Community, Host Officials, and Officials from Florida on the Goals of the Summit, in *gopher://summit.fiu.edu/00/Updates/clinton-remarks.txt*.

Development, Free Trade and Sustainable Development in the Americas"[100], and a more detailed Plan of Action[101].[102]

The Declaration of Principles calls for the promotion of economic progress through the creation of a Free Trade Area of the Americas in which barriers to trade and investment would be eliminated progressively. The agreed deadline for the conclusion of the negotiations is the year 2005. Such negotiations will consider the existing regional and sub-regional agreements to deepen and broaden the hemispheric integration process.

In addition, the Declaration calls for further action in the field of human and minority rights, corruption, drugs, terrorism, infra-structure, science and technology, tourism, poverty, education, sustainable development and the protection of the environment. The Declaration of Principles calls also for the "... participation of the private sector, labor, political parties, academic institutions and other non-governmental actors and organizations in both our national and regional efforts, thus strengthening the partnership between governments and society".

While stating that the creation of the FTAA will be in accordance with the GATT/WTO[103] rules and will not raise new barriers to trade, the Plan of Action is a document considering the major steps which will be taken in four broad areas: (a) Preserving and Strengthening the Community of Democracies of the Americas; (b) Promoting Prosperity Through Economic Integration and Free Trade; (c) Eradicating Poverty and Discrimination in Our Hemisphere; and (d) Guaranteeing Sustainable Development and Conserving Our Natural Environment for Future Generations. In

---

[100]Published in [1994] 15 *BILA* 241-244.
[101]Published in [1994] 15 *BILA* 244-260.
[102]Both the Declaration of Principles and the Plan of Action were signed virtually by all Heads of States of the Continent with the exception of Fidel Castro.

between, there are twenty three principles in which action shall be pursued. These goals will be sought with the co-operation of the institutions of the regional and sub-regional agreements and, in particular, with the technical assistance of several international organisations such as the OAS, IDB, UN Economic Commission for Latin America and the Caribbean, Pan-American Health Organisation (PAHO), the World Bank and other UN agencies which are active in the hemisphere. For this purpose a schedule of negotiations was established as follows.

In January 1995 the working programme started with the creation of schedules for the OAS Special Committee on Trade[104]. In June 1995, Ministers of trade-related areas of the thirty four nations met in Denver/Colorado, the USA, to analyse the report of the SCT and to assess areas of immediate action. As a conclusion of this gathering, Ministers released the "Denver Declaration"[105] which agrees on an immediate programme to be prepared for the initiation of negotiations of the FTAA, which shall be consistent with the rules of the World Trade Organization (WTO), and shall take into consideration opportunities to facilitate the integration of less-developed economies into the process, and increase their level of development.

The Denver Declaration establishes seven Working Groups in the following areas: Market Access[106]; Customs Procedures and Rules of Origin[107]; Investment[108];

---

[103]Plan of Action, Chapter II, 9 (1). Also, countries which are not yet Members of the GATT/WTO are encouraged to do so.

[104]The OAS was in charge of the Special Committee on Trade (SCT), "... to assist in the systematization of data in the region and to continue its work on studying economic integration arrangements in the Hemisphere, ..." (Plan of Action, Chapter II, 9 (7)).

[105]In *http://americas.fiu.edu/documents/950630.htm*.

[106]The Working Group on Market Access will organise a comprehensive database on market access barriers covering all industrial and agricultural products and make specific recommendations in this regard (Denver Declaration, Annex, point (1)).

[107] The Working Group on Customs Procedures and Rules of Origin will compile a comprehensive inventory of Hemisphere customs procedures, determining the feasibility of publishing a Hemisphere Guide to Customs Procedures; develop features for a system of rules of origin; identify areas for technical co-operation in customs operation; and make recommendations for the negotiations on rules of origin (Denver Declaration, Annex, point (2)).

Standards and Technical Barriers to Trade[109]; Sanitary and Phitosanitary Measures[110]; Subsidies, Antidumping and Countervailing Duties[111]; and Smaller Economies[112].[113] It was also decided that next Ministerial Meeting should create working groups in the areas of government procurement; intellectual property rights[114]; services; and competition policy. These four additional working groups were eventually established during the Second Ministerial Trade Meeting, held in Colombia on 21 March 1996[115],

---

[108]The Working Group on Investment will create an inventory of investment agreements and treaties that exist in the region, determining areas of commonality and divergence and make recommendations (Denver Declaration, Annex, point (3)).

[109] The Working Group on Standards and Technical Barriers to Trade will compile information on the bodies that exist which are charged with conformity assessment to technical regulations in the continent; recommend methods to promote understanding of the WTO Agreement on Standards and Technical Barriers to Trade; and make recommendations on ways to enhance transparency (Denver Declaration, Annex, point (4)).

[110]The Working Group on Sanitary and Phitosanitary (SPS) Measures will create an inventory of all agreements on SPS in the continent; promote understanding of the WTO Agreement on Sanitary and Phitosanitary Measures; enhance mutual understanding of the scientific basis for SPS certification procedures; and compile the methods used for risk assessment in the continent, with a view to work toward common approaches (Denver Declaration, Annex, point (5)).

[111] The Working Group on Subsidies, Antidumping and Countervailing Duties will identify agricultural export subsidies and other export practices (recommending ways to address trade-distorting export practices for agricultural products that are traded in or with the hemisphere); promote understanding of the WTO obligations in the area of subsidies; review information on the dumping and subsidies laws of the countries of the Americas; exchange views on the application and operation of trade remedy laws regarding subsidies and dumping; and make recommendations (Denver Declaration, Annex, point (6)).

[112] The Working Group on Smaller Economies will identify and assess the factors affecting the participation of smaller economies in the FTAA; identify and examine ways to facilitate their participation in the establishment of the free trade area; and make recommendations on measures to be taken and issues to be considered in the negotiations of the FTAA (Denver.Declaration, Annex, point (7)).

[113]Denver Declaration, para. 5.

[114]Following the Ministerial Meeting of June 1995, the US distributed a proposal on the terms of reference for the Working Group on Intellectual Property Rights (**US Government**, FTAA Working Group on Intellectual Property - Proposed Terms of Reference - 5 December 1995, in *http://americas.fiu.edu/inside/index.html*) to be established during the Second Ministerial Meeting in Colombia. This proposed terms of reference suggested by the US allows the Working Group to go beyond the data-collection-oriented tasks given to the other working groups, suggesting that they should identify ways to eliminate possible restrictions on the market access of intellectual property-related products and services; recommend ways to promote the understanding of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights; and identify measures to improve the administration of IPRs, such as the facilitation of applications and granting procedures.

[115]At the first meeting in Denver, Ministers accepted the invitation of the government of Colombia to host the second meeting (Denver Declaration, para. 12). Prior to the Second Ministerial Meeting, the private sector of the thirty four countries gathered in Cartagena de Indias, Colombia, from 18 to 21 March 1996, to discuss further its participation in the integration process. Several questions have been taken into account, such as the opportunities for the private sector in the FTAA, the effects of national economic policy on the process of creating the FTAA, and investments. Under the auspices of four committees the "Americas Business Forum" analysed further the following issues: trading

which also analysed the final report of the SCT and received the reports of the working groups mentioned above[116, 117].

The four working groups created by the Cartagena Declaration have the following plan of action[118]:

> (1) The Working Group on Government Procurement, which will be chaired by a representative of the US[119], has the following tasks: to collect, systemise and create an inventory of legislation, regulations and procedures in the national level and in the integration schemes and other existing agreements in the hemisphere; to compile data on purchases or goods and services by central governments, including state-owned undertakings; to identify areas of commonality and divergence; to recommend methods to promote understanding of the WTO Government Procurement Agreement; to recommend methods to promote transparency; and to make recommendations.
>
> (2) The Working Group on Intellectual Property Rights, which will be chaired by a representative of Honduras[120], has the following tasks: to create an inventory of the intellectual property agreements, treaties and arrangements, including international agreements to which countries are parties, as well as to compile an inventory of national intellectual property laws, regulations and enforcement procedures, identifying, on the basis of this information, areas of commonality and divergence; to recommend methods to promote understanding and implementation of the TRIPS Agreement; identify possible areas of technical assistance, including administration and enforcement of IPRs; to analyse the implications of emerging technologies for IPRs protection in the FTAA; and to make recommendations.
>
> (3) The Working Group on Trade on Services, which will be chaired by a representative of Chile[121], has the following tasks: to undertake conceptual background work on the nature of trade in services, including the relationship with other working groups, particularly the Working Group on Investment[122]; to compile a comprehensive inventory of agreements covering trade in

---

strategies in the FTAA: opportunities for the private sector in the development, construction and operation of infrastructure; globalisation of production process; and human sustainable development and environmental preservation (**FTAA**, The Americas Business Forum, Cartagena de Indias Colombia, March 18-21, 1996, *http://americas.fiu.edu/documents/960130.htm*).

[116]Second Ministerial Trade Meeting, Cartagena, Colombia, 21 March 1996, Joint Declaration, hereinafter the "Cartagena Declaration" (in *http://americas.fiu.edu/documents/960321a.htm*), para. 6. For the information on the establishment of the four additional working groups, see Cartagena Declaration, para. 11.

[117]*Cf.* notes 106 to 112, *supra*, for the plan of work of the working groups established in the First Ministerial Trade Meeting.

[118]The plan of action for the new four working groups is available in Annex I of the Cartagena Declaration (in *http://americas.fiu.edu/documents/960321a.htm*).

[119]Cartagena Declaration, Annex II.

[120]*Ibid.*

[121]*Ibid.*

[122]*Cf.* note 108, *supra*.

services and determine areas of commonality and divergence; to create a comprehensive inventory of measures affecting trade in services and identify steps to enhance transparency and facilitate trade; to recommend methods to promote understanding and implementation of the WTO General Agreement on Trade in Services (GATS); and to make recommendations.

(4) The Working Group on Competition Policy, which will be chaired by a representative of Peru[123], has the following tasks: to promote understanding of the objectives and operation of competition policy; to compile an inventory of national laws and regulations, as well as competition policy agreements, treaties and arrangements, identifying, on the basis of this information, areas of commonality and divergence; to identify co-operation mechanisms among governments aiming at ensuring the effective implementation of competition policy laws; to recommend ways to assist countries to implement their competition policy laws; to exchange views on the application and operation of competition policy regimes and their relationship with trade; and to make recommendations.

During the Second Ministerial Trade Meeting major points of conflict between the US and other Latin American nations, notably Brazil, took place. Particularly, the continuous efforts from US representatives to include in the discussion labour and environmental regulations. Virtually all Latin American States opposed the inclusion at this stage of a deeper discussion on regulations in these fields. Although the position of the latter prevailed, the US managed to include in the Cartagena Declaration a statement affirming that the Ministers recognise "... the importance of the further observance and promotion of worker rights and the need to consider appropriate processes in this area ..."[124].

Another reason for conflicts, particularly between Brazil and the US, was related to the Costa Rican candidature to host the 1997 Ministerial Trade Meeting. Brazil had already offered to host this meeting in Denver, and it seemed that all countries had agreed with that. Between the Denver and the Cartagena meetings, however, Costa Rica offered its candidature which was apparently supported by US

[123]Cartagena Declaration. Annex II.

representatives. At the end of the Cartagena meeting, it was finally agreed that Brazil would host the Third Trade Ministerial Meeting and Costa Rica would host the fourth one, in 1998[125, 126].

There are three major routes to be followed towards the establishment of the FTAA. A possible path is through the negotiations for broadening the scope of NAFTA with the possibility of accepting all countries. Another solution is to seek the conclusion of arrangements between the existing sub-regional or regional mechanisms, until the formation of a broadened network covering all the countries of the Americas is reached. Another possibility is to negotiate a conclusive arrangement with the participation of all countries of the Americas and covering the issues as a whole. The latter is most unlikely. Generally speaking, the US supports the first way, and others countries, such as Brazil, support the second route. On the one hand, the US wishes NAFTA to lead the process of continental integration. Brazil, on the other, wants to have the MERCOSUL playing a leading role for gathering countries together into a broader Latin American free trade arrangement.

While it is reasonably difficult to predict what is going to come from these negotiations, and even if they are going to have any practical success in the near future, what is likely to happen at some point is that the negotiations will be carried out between NAFTA and MERCOSUL, leaving other countries with no other option than joining them.

---

[124] *Ibid.*, para. 15.
[125] Cartagena Declaration. para. 16.
[126] **Carlos Eduardo Lins da Silva**. Comércio Exterior é Foco de Tensão com os EUA. *Folha de São Paulo*. 29 March 1996.

2. AN OVERVIEW OF THE PROCESS IN THE MERCOSUL

In the first Section of this Chapter, a brief historical background of the integration process of Latin America was provided. In a general sense, these historical facts are the origins of the MERCOSUL. The political will to promote mechanisms for commercial and economic co-operation among Latin American countries, as it has been seen, is the basis upon which the MERCOSUL has been conceived, and these initiatives started formally more than thirty years ago.

Economic integration is a very important issue for current Brazilian foreign policy. It is, nevertheless, necessary to remember that not only the policy makers, but also the Brazilian legislature have given great importance to the discussion of Latin American integration, by the inclusion of a postulate, among Brazilian constitutional principles, that Brazil "... shall seek the economic, political, social and cultural integration of the people of Latin America, with a view towards forming a Latin-American community of nations"[127]. Though this Brazilian constitutional principle refers only to Latin American integration, apparently limiting the territorial application of the concept - excluding the US and Canada - it is possible to assume that such constitutional idea is rather a goal that Brazilian government must seek, than a principle which limits the geographical application of the intention of the legislature. The integration process in the MERCOSUL is undoubtedly more feasible than a Latin American-type of process. It does not diminish, however, the intentions of setting up a continental form of approximation on a practical basis.

---

[127] Brazilian Federal Constitution, of 5 November 1988, Art. 4, Sole paragraph. Translation from **Keith S. Rosenn**, Brazil - Supplement, in **Albert P. Blaustein & Gisbert H. Flanz** (ed.), Constitutions of the Countries of the World. New York: Oceana Publications Inc. (1993). Release 93-2. All the translation of the Brazilian constitutional provisions in this and the following Chapters are taken from the reference above.

It would appear that economic theories and doctrines have been influencing the drawing-together of the four countries of the Southern Cone of Latin America, which would place the present work on a second level of importance. However, this assertion is untrue, if one takes into account the process as a whole. The rationale for the unification of national markets among the four countries has indeed a bias to consider the economic advantages of the process in its entirety. But, beyond economic theories, it is necessary to recall that the process is fundamentally political, and the necessary performance of political actions and intentions is made material by the law and made effective by national courts. The analysis of the entire process is very complex and all the issues involved (economic, political, legal, social, cultural, etc.) play a determinant part in the foundation and functioning of the integrating system. This Section shall, nevertheless, pay more careful attention to the political and legal aspects of the MERCOSUL.

The present Section will, therefore, provide a general view of the process which culminated with the MERCOSUL, affording a descriptive analysis of the institutional characteristics, and of the mechanism for the operation of the common area.

2.1. Origins and sources

Following the advice of Paulo Roberto de Almeida, it is important to emphasise that the first thing to be said about the MERCOSUL is that its creation is late by at least half a century[128]. As has been seen in the foregoing Section, even the creation of the LAFTA was based essentially on the initiatives of the countries of the Southern Cone,

a fact which places them in a leading position towards the formation of a commercially integrated area.

Recent facts, however, describe more evidence for the motivation to integrate, particularly, the markets of Argentina and Brazil. The first action towards the approximation of the two countries was primarily political. In 1980, Argentina and Brazil agreed upon a co-operation programme in the field of atomic energy. Later, in 1982 Brazil expressly supported Argentina in the Falklands war. Then, the political process of redemocratisation of both countries, which occurred almost during the same period, naturally gave more support to further political endeavours to discuss, on a more practical basis, the approximation of the two economies.

The initial formalisation of the economic and commercial approximation between Argentina and Brazil occurred in 1985, with the Declaration of Iguaçu. At that time, a committee was created to study the forms and modalities of a future economic co-operation arrangement between the two countries. The conclusions of this committee led to the signature, on 29 July 1986, of the Agreement on Argentine-Brazilian Integration[129]. This Agreement, which calls for the establishment of a common economic space, creates the first formal instrument of the integration process (the Programme for Economic Integration and Co-operation - PEIC) which led the two countries to sign a total of twenty four Protocols dealing with different sectors of the economy, like agriculture, foodstuff, financial matters, trade preferences, steel industry and other industrialised products.

---

[128]**Paulo Roberto de Almeida**, note 3, *supra*, p. 72. He obviously refers to the project of Argentina and Brazil during the early 1940s on the negotiations of an integration scheme between the two countries (in Section 1, note 3, *supra*).

[129]As published in 27 *ILM* 901 (1988). This agreement came into force on 1 January 1987.

This programme was followed by the signing, on 29 November 1988, of the Treaty of Integration, Co-operation and Development[130], which established a deadline of ten years for the creation of a common economic space between Argentina and Brazil. The mechanism utilised for the attainment of this goal was the elimination of all tariff and non-tariff barriers, as well as the harmonisation of macro-economic policies.

Soon after, in July 1990, both countries decided to accelerate the integrating process and signed the Act of Buenos Aires[131] which established a more ambitious deadline (31 December 1994) for the creation of a Common Market between Argentina and Brazil. Paraguay and Uruguay later joined the negotiations which Argentina and Brazil were carrying out on a bilateral basis. The outcome of these negotiations was the signing of the Treaty Establishing a Common Market between the Argentine Republic, the Federative Republic of Brazil, the Republic of Paraguay and the Eastern Republic of Uruguay, on 26 March 1991[132].[133]

It is also worth noting that the legal sources of the MERCOSUL are not only the Treaty of Asuncion and its protocols, and the decisions of the organs thereby created, but further, the complementary agreements signed in the framework of the LAIA. By virtue of Article 8, Treaty of Asuncion, "... States Parties undertake to abide by commitments made prior to the date of the signing of this Treaty, including

---

[130]Portuguese version published in **Paulo Roberto de Almeida**, note 69, *supra*.

[131]As mentioned by **Paulo Roberto de Almeida**, note 3, *supra*, pp. 78-79.

[132]30 *ILM* 1041 (1991). Hereinafter the "Treaty of Asuncion" (Art. 23). The Treaty of Asuncion came into force on 30 November 1991.

[133]The historical information provided in the preceding paragraphs was borrowed from the following publications: **José Angelo Estrella Faria**, O MERCOSUL: Princípios, Finalidade e Alcance do Tratado de Assunção, Brasília: MRE/SGIE/NAT (1993), pp. 162-168; **Paulo Roberto de Almeida**, note 3, *supra*, pp. 75-79; **Gloria Worcel**, El MERCOSUR en el Periodo de la Transicion: Funcionamento Institucional, Participación Empresaria e Impacto Sobre el Comercio, Buenos Aires: CEPAL [ECLA], Documento de Trabajo N. 44, LC/BUE/L.126, May 1992, 2-3; and **Celso Luiz Nunes Amorim**, 'O Mercado Comum do Sul e o Contexto Hemisférico, [1991] 7 *Boletim de Diplomacia Econômica* 3-8, at pp. 5-7.

agreements signed in the framework of the Latin American Integration Association (...), and to coordinate their positions in any external trade negotiations they may undertake during the transition period". For the purpose of the application of this provision, there are several rules which shall be followed by the States Parties of the MERCOSUL.

States Parties shall therefore avoid affecting the interests of other States Parties or of the envisaged Common Market in agreements that they may conclude with other countries members of the LAIA[134], or in any trade negotiations they may conduct by themselves[135]. They shall also consult among themselves whenever negotiations of tariff reductions for the formation of other free trade areas take place[136]; and they are obliged to extend to other States Parties of the MERCOSUL any advantage, favour, exemption, immunity or privilege granted to a product originating in or destined to third countries which are not members of the LAIA[137].[138]

2.2. General structure of the Treaty of Asuncion

The Treaty of Asuncion is a quadrilateral agreement with twenty four Articles, five Annexes and three Declarations. The rationale of the Treaty of Asuncion is the acceleration of the process of economic development of its participants, with social justice; the promotion of scientific and technological development; and the modernisation of the economies of the States Parties for the expansion of the supply and improvement of the quality of available goods and services, with a view to

---

[134] Treaty of Asuncion, Art. 8 (b).
[135] *Ibid.*, Art. 8 (a).
[136] *Ibid.*, Art. 8 (c).
[137] *Ibid.*, Art. 8 (d).
[138] For more detailed discussion on the instruments that were into force during the transitional period by virtue of Article 8 of the Treaty of Asuncion, see **José Angelo Estrella Faria**, note 133, *supra*, pp. 164-168.

enhancing the living conditions of the populations of the Parties.[139] All this takes into account the necessary insertion of their economies in the international arena, in particular considering the regionalisation trends happening all over the world, with a view to furthering the efforts to bring about a Latin American Common Market[140].

The establishment of a common market, by 31 December 1994, was designed to be achieved taking into account the following instruments: (a) the establishment of a system of free movement of goods, services and "factors of production"[141] through, *inter alia*, the elimination of customs duties and non-tariff restrictions on the movement of goods, and any other equivalent measures; (b) the establishment of a common external tariff and the adoption of a common trade policy in relation to third parties or group of States, and the co-ordination of positions in regional and international economic and commercial forums[142]; (c) the co-ordination of macro-economic and sectoral policies between the States Parties in the areas of foreign trade, agriculture, industry, fiscal and monetary matters, foreign exchange and capital, services, customs, transport and communications, or any other that may be deemed necessary; and (d) the harmonisation of legislation in the relevant areas with a view of strengthening the integration process.[143]

---

[139]Treaty of Asuncion, Preamble.

[140]*Ibid.*

[141]The expression "factors of production" includes two elements: capital and work force. It is also possible to use the expression "free circulation of people", as comprising workers and undertakings, and "free circulation of capital", referring only to material investments. As formally speaking the Treaty of Asuncion has not the object of a full political union, consequently the "free circulation of people" as a result of the process is related merely with its characteristics as "factors of production" (**José Angelo Estrella Faria**, note 133, *supra*, p. 41).

[142]Such as the GATT/Uruguay Round, the LAIA and the negotiations towards the FTAA.

[143]Treaty of Asuncion, Arts. 1 and 5. Article 5, in fact, decides upon the main instruments which shall be used for the achievements of the objectives of an area free of restrictions, within the deadline imposed by Article 1, such as the establishment of a liberalisation programme which includes, *inter alia*, the progressive and gradual reduction of tariffs and non-tariff measures; the co-ordination of macro-economic policies; a common external tariff; and the adoption of sectoral agreements.

The Treaty of Asuncion recognises the economic situation of Paraguay and Uruguay and grants them an extra period of one year, *i.e.* until 31 December 1995, for the full elimination of restrictions[144]. In addition, the States Parties adopted general rules of origin for the transitional period (Annex II)[145], a system for the settlement of disputes (Annex III)[146], and safeguard clauses (Annex IV).[147] They also agree upon the co-ordination of their domestic policies with a view of drafting common rules on competition[148], and they declare their will to promote closer co-operation with Bolivia and Chile[149].

Accession to the MERCOSUL by other members of the LAIA shall be through negotiation, and approval of the application for accession requires an unanimous decision of the States Parties. Applications from members of other sub-regional agreements who want to accede to the integrating process of the MERCOSUL may be considered only five years from the entry into force of the Treaty of Asuncion, while applications from other members of LAIA, who do not participate in sub-regional agreements, may be considered before this date.[150]

A State Party who wishes to withdraw from the Treaty of Asuncion has to inform the other States Parties of its intention and shall submit the document of

---

[144]*Ibid.*, Annex I, Art. 1.

[145]By Decision of Council of the Common Market MERCOSUL/CMC.DEC. N. 2/1991(published in [1993] Special Edition *BILA* 30), the MERCOSUL establishes a more detailed set of rules for the certification of the origin of products.

[146]The Protocol of Brasilia for the Settlement of Disputes (MERCOSUL/CMC/DEC. N. 1/1991, in [1993] Special Edition *BILA* 30) sets up the mechanisms for the resolution of conflicts during the transitional period, which will be further discussed in Paragraph 2.2.2, *infra*.

[147]Treaty of Asuncion, Art. 3.

[148]*Ibid.*, Art. 4. Additionally, States Parties are requested to apply their domestic legislation to restrict the importation of products, originating from third countries, whose prices are influenced by subsidies, dumping or any other unfair practice. The negotiations towards common rules against unfair competition is further discussed in Chapter 6, Section 2, Sub-section 2.3, *infra*.

[149]Declaration Nos. 2 and 3, respectively (both published in 30 *ILM* 1063 (1991)).

[150]Treaty of Asuncion, Art. 20.

denunciation within sixty days[151]. Once the denunciation is formalised, the rights and obligations of the denouncing party shall cease, while those relating to the liberalisation programme will continue for a period of two years counted from the date of the formalisation[152].

One of the main problems of the Treaty of Asuncion is that it created an integrating process with the characteristics of a free trade zone, but did not provide for a juridical personality under international law for this process. This was, at the beginning, viewed as a possible threat to the process as a whole. This situation was later re-arranged, as will be analysed below in Sub-section 2.3, Paragraph 2.3.1.

2.2.1. Basic principles

The Treaty of Asuncion is based on the principles of gradualism, flexibility and balance[153], reciprocity[154] and consensus[155]. All these principles seem to work together for the attainment of the main goal of establishing a common market between the participating countries. This Paragraph will discuss briefly the application of these principles in the context of the formation of the MERCOSUL.

The principle of gradualism implies that the process of liberalisation of trade for the establishment of the MERCOSUL shall be done through successive stages, in growing intensity. The example of Article 3 of Annex I, of the Treaty of Asuncion, makes this principle clearer. This provision affirms that tariff reductions will take place in a gradual, linear and automatic basis, benefiting the listed products classified in accordance with the tariff nomenclature of the LAIA, and that the date/percentage

---

[151] *Ibid.*, Art. 21.
[152] *Ibid.*, Art. 22.
[153] *Ibid.*, Preamble
[154] *Ibid.*, Art. 2.
[155] *Ibid.*, Art 16.

of tariff reduction would take place as follows: 30 June 1991 (47%); 31 December 1991 (54%); 30 June 1992 (61%); 31 December 1992 (68%); 30 June 1993 (75%); 31 December 1993 (82%); 30 June 1994 (89%); and 31 December 1994 (100%). This principle suggests that the States Parties of the MERCOSUL intended to give time for their economies, and for their private actors, to adjust themselves to a partial and selective liberalisation of markets.

The principle of flexibility indicates that the outline of the liberalisation programme, its deadlines and plans, will not have a rigid character and will be flexible, to be changed in accordance with the pace of the establishment of the Common Market. This principle, then, gives the States Parties and the process itself the possibility to adjust the liberalisation programme constantly, for the achievement of the goal of creating the Common Market. As pointed out by Estrella Faria[156], the lack of definition of this principle in the text of the Treaty of Asuncion alludes to two different types of interpretation of the application of the principle. Firstly, it is suggested that in considering the application of the Treaty of Asuncion, the principle of flexibility works as a guideline for the procedures that the governments of the participating countries will take to put the liberalisation programme effectively into practice. In this case, the principle should not any have further purpose. Secondly, from examination of the application of this principle in the context of the Treaty of Asuncion, the notion of flexibility constitutes one of the basic elements for the interpretation of the provisions of the treaty. This is very much a result of the general wording of the Treaty of Asuncion, which suggests that the principles on which it will be based are of general understanding and generally applicable in the context of international law.

The principle of balance may suggest that the Treaty of Asuncion should avoid the specialisation of the sectors of the economy. It is not clear, however, how this specialisation would take place and, further, how such specialisation would threaten the integration process in its entirety. Again, as highlighted by Estrella Faria[157], the application of the principle of balance could take into account the negative aspect of the balance. This means not the consideration of the balance that is supposed to be reached by the different economic sectors during the integration process, but the avoidance of a situation which may be unbalanced. The Treaty of Asuncion has nevertheless provided for mechanisms to guarantee the balance of competition among industrial sectors by the safeguard measures provided for the transitional period.

Finally, the principle of reciprocity, which indicates that the duties and obligations of the States Parties shall follow such a principle, differs in essence from the other set of principles listed in the Preamble of the Treaty of Asuncion. This principle is not designed directly for the attainment of the objectives of the treaty, but aims at regulating the formal (legal) relationship of the contracting parties within the context of the integration process. [158]

2.2.2. Institutional matters

The Treaty of Asuncion established two organs for the execution of the integration process: the Council of the Common Market (CCM) and the Common Market Group (CMG)[159]. The highest organ of the MERCOSUL is the CCM, which has the responsibility for political leadership and for decision-making to ensure compliance

---

[156]Note 133, *supra*, pp. 5-6.
[157] *Ibid.*, p. 14.
[158]For a further analysis of the application of the principles of gradualism, flexibility, balance and reciprocity, and its contradictions for their application during the transitional period established by the Treaty of Asuncion, see **José Ângelo Estrella Faria**, note 133, *supra*, Chapter 1.

with the objectives set out by the Treaty of Asuncion[160]. The CCM is composed by the Ministers of Foreign Affairs - who co-ordinate the meetings of the CCM[161] - and the Ministers of Economy of the States Parties, and shall meet at least once a year with the participation of the Presidents of the participating countries[162].

The CMG, which is co-ordinated by the Ministries of Foreign Affairs, is the executive organ of the MERCOSUL and is in charge of the following duties: to monitor compliance with the treaty; to take necessary steps to enforce the decisions of the CCM; to propose measures for applying the trade liberalisation programme; to co-ordinate macro-economic policies; to negotiate agreements with third parties; to draw up programmes of work to ensure progress of the process; to decide upon its own rules of procedure; and to create any working groups it deems necessary for the attainment of the objectives laid out by the Treaty of Asuncion, in addition to those provided by Annex V, which will be described later in this Paragraph.[163]

The CMG consists of four members and four alternates for each State Party, representing the Ministry of Foreign Affairs, the Ministry of Economy or its equivalent (areas of industry, foreign trade and/or economic co-ordination), and the Central Bank. When working towards proposing measures as part of its work during the transitional period, the CMG may call on representatives of other government agencies or ministries, or the private sector.[164] The CMG has an administrative

---

[159]Treaty of Asuncion, Art. 9.
[160]*Ibid.*, Art. 10.
[161]*Ibid.*, Art. 12. The Presidency of the CCM shall rotate among the States Parties, in alphabetical order, for periods of six months, and other ministers or ministerial authorities may be invited to participate of the meetings of the CCM (*Ibid.*).
[162]*Ibid.*, Art. 11.
[163]*Ibid.*, Art. 13.
[164]*Ibid.*, Art. 14.

secretariat, with headquarters in Montevideo, with the functions of keeping the CMG's documents and report on its activities[165].

For the purposes of co-ordinating macro-economic and sectoral policies, the CMG established ten working groups. Later, Resolution MERCOSUL/GMC/RES. N. 11/1991[166], established the Sub-group N. 11, entitled Labour Matters. Then, by Resolution MERCOSUL/GMC/RES. N. 11/1992[167], this Sub-group was renamed to Labour Relations, Employment and Social Security.

Sub-group 1, on Commercial Issues, has discussed, *inter alia*, common regulations on competition law, including the drafting up of an Anti-dumping Code, and common policies on safeguards measures and customs regimes. Sub-group 1 has also identified and compared different instruments, in particular those related with fiscal and monetary matters, and a common customs nomenclature.

Sub-group 2, on Customs Issues, has drafted a glossary for the MERCOSUL, harmonising terms and definitions; and has discussed customs legislation for the internal and external relationship between the States Parties of the MERCOSUL and also with third parties. Sub-group 2 has also dealt with the comparison between the national legislation on sanitary and phitosanitary measures, border control and tourism.

Sub-group 3, on Technical Standards, has, *inter alia*, analysed technical norms relating to the transport and trade in the MERCOSUL and biosafety regulations. Sub-group 4, on Fiscal and Monetary Policies relating to Trade, has dealt with exchange regimes, regulations for the operations with foreign currencies, Stock Markets regulations, etc.

---

[165] *Ibid.*, Art. 15.
[166] Published in [1993] Special Edition *BILA* 100.
[167] Published in [1992] 4 *BILA* 25.

Sub-groups 5 and 6, on Inland and Maritime Transport respectively, have considered the harmonisation of norms for the transport within the MERCOSUL, both by road or by sea or river.

Sub-group 7, on Industrial and Technological Policy, has considered, *inter alia*, an approach towards a common science and technology policy, including discussions on the harmonisation of national intellectual property laws, transfer of technology regulations, forms to support a closer link between academia and private sectors, and environmental protection.[168]

Sub-group 8, on Agricultural Policy, has carried out studies on, *inter alia*, agriculture insurance, irrigation, agricultural equipment, financial mechanisms to develop the agriculture of the four countries, storage, social programmes, training, rural electrification, productivity and quality, and systems for the commercialisation of agricultural products.

Sub-group 9, on Energy Policy, studied policies on all types of energy, including electricity, coal, petrol and others, aiming to define the national mechanisms for the promotion of institutional and organisational structure for the sector, taking also into consideration common measures aiming at the protection of the environment.

Sub-group 10, on Co-ordination of Macro-economic policies, considered the aspects of the relationship between the States Parties of the MERCOSUL and the outside world, aiming to reach a common view towards third countries. This Sub-group's intention was, essentially, to guarantee the necessary measures that would support the setting up of a common external tariff. Some comparative analysis was

[168]The work carried out by Sub-group 7, in particular the issues that has arisen from the Committee on Intellectual Property, is discussed in more detail in Chapter 5, *infra*.

also delineated to understand some intra-trade MERCOSUL measures. It is also in Sub-group 10 that a Committee has been established to discuss the creation of common rules for protection against unfair competition within the integrated area[169].

Sub-group 11, on Labour Relations, Employment and Social Security, analysed, in a comparative basis, the national legal systems for regulating the relationship between employers and employees, wages, social contributions, employment, the free circulation of workers, training, etc. This Sub-group also considers aspects of regulatory measures for health and safety in the context of working conditions. Aiming to pay more attention to the views of the workers, the most important Trade Unions were also represented in this Sub-group.

The Treaty of Asuncion, in Article 24, calls also for the establishment of a Joint Parliamentary Commission with a view at co-ordinating the work of the diplomatic and sectoral negotiations with their implementation into national legal systems. The organisational structure described above is also represented in Chart 3, Appendix I, *infra*.

By virtue of Article 3[170] and by Annex III[171] of the Treaty of Asuncion, the Protocol of Brasilia for the Settlement of Disputes[172] was established for regulating the resolution of conflicts between States Parties themselves that would eventually arise from the interpretation or application of the Treaty of Asuncion or of the

---

[169]The issues on the harmonisation of anti-competitive measures is further discussed in Chapter 6, Section 2, Sub-section 2.3, *infra*.

[170]Which calls for the adoption of, *inter alia*, a system for the settlement of disputes for the transitional period.

[171]Treaty of Asuncion, Annex III says that within 120 days from the entry into force of the Treaty of Asuncion, a system for the settlement of disputes for the transitional period should be established (Annex III, point 2), taking into account that until 31 December 1994 a definite system should be established (*Ibid.*, point 3). A definite system for the resolution of conflicts has been established and will be further discussed in Sub-section 2.3, Paragraph 2.3.1, below.

[172]Approved by Decision of the Common Market Council MERCOSUL/CMC/DEC. N. 01/1991, note 146, *supra*. Hereinafter the "Protocol of Brasilia". The full text of the Protocol of Brasilia is published in **Paulo Roberto de Almeida**, note 69, *supra*, pp. 132-140.

agreements reached within its framework, as well as disputes related to the interpretation or application of the decisions of the CCM and of the resolutions of the CMG[173].

The system is based on the establishment of an *ad hoc* Tribunal, which would be established after the following procedure. Firstly, Parties should try to resolve their conflicts by direct negotiations[174], and should inform the CMG, through its Administrative Secretary, about the actions that have been taken for and during the direct negotiations[175].

If such negotiations do not lead, or lead partially, to the solution of the controversy, any of the Parties may submit it to the CMG, which will analyse the circumstances, allowing the Parties to lay down their positions and, if necessary, the CMG will call in a group of selected experts[176].[177] At the end of this stage of the proceedings, which shall last for up to thirty days counted from the date that the controversy was submitted to the CMG[178], the CMG will formulate recommendations to the States Parties in the dispute, aiming at its solution[179].

If neither of these procedures succeed in resolving the dispute, any of the States Parties may inform the Administrative Secretary that it intends to use Arbitration proceedings for the settlement of the controversy[180]. An *ad hoc* Tribunal,

---

[173]Protocol of Brasilia, Art. 1.
[174]*Ibid.*, Art. 2.
[175]*Ibid.*, Art. 3 (1). Direct negotiations may not exceed fifteen days after the dispute was raised by one of the Parties (*Ibid.*, Art. 3 (2)).
[176]Each State Party will designate a list of six experts, and such a list will be registered in the Administrative Secretary (*Ibid.*, Art. 30 (2)).
[177]*Ibid.*, Art. 4. The costs of this stage of the proceedings will be paid equally by both Parties (*Ibid.*, Art. 4 (3)).
[178]*Ibid.*, Art. 6.
[179]*Ibid.*, Art. 5.
[180]*Ibid.*, Art. 7 (1). After receiving such a communication the Administrative Secretary will inform at once the other Party (ies) in the dispute and the CMG (*Ibid.*, Art. 7 (2)).

composed by three arbitrators, will then be established[181]. Each State Party of the dispute will designate one arbitrator and an alternate, and a third one will be chosen by both of them, who may not be a national of one of the Parties in the dispute and who will preside over the Tribunal[182]. In the case of any dispute for choosing or appealing against a choice of an arbitrator, the Administrative Secretary will be in charge of designating the conflicting name[183].

Once the Arbitration Tribunal is established and operating, it will fix its own rules of procedure and will designate where it is going to take place, in accordance with the opinion of the Parties[184]. Then, the States Parties, through their representatives before the Tribunal[185], will inform the Arbitration Tribunal about the circumstance and will brief the Tribunal with their own justification and reasons for the dispute[186]. In case the Arbitration Tribunal deems necessary the issue of preliminary rulings, it may do so, and the States Parties shall comply with such ruling at once or within the period specified in the ruling[187].

The Tribunal shall deliberate upon a dispute within up to ninety days from the date its President was designated and its ruling shall be adopted by majority. The votes of the arbitrators will not be accompanied by any justification[188]. All decisions

---

[181] *Ibid.*, Art. 9 (1).
[182] *Ibid.*, Art. 9 (2). States Parties must designate a list of ten arbitrators each, which will be kept by the Administrative Secretary and from where the arbitrators in a dispute will be chosen from (*Ibid.*, Art. 10). This list must be composed by legal specialists which are recognised as competent in matters which may be the object of a controversy (*Ibid.*, Art. 13).
[183] *Ibid.*, Arts. 9 (2) (i), 11. and 12 (1).
[184] *Ibid.*, Art. 15.
[185] *Ibid.*, Art. 17.
[186] *Ibid.*, Art. 16.
[187] *Ibid.*, Art. 18.
[188] *Ibid.*, Art. 20.

of an *ad hoc* Arbitration Tribunal are binding upon the Parties as *res judicata*, and there are no grounds for an appeal[189].

The Protocol of Brasilia provides, also, for a system of resolution of controversies raised by a natural person or legal entity who is affected by a legal or administrative measure taken by a State Party, as well as a discriminatory measure or those which lead to a position of unfair competition, when such measures are against the Treaty of Asuncion, its protocols or agreements signed under it, Decisions of the CCM and Resolutions of the CMG.[190]

A natural person or legal entity which intends to resolve a dispute against a State Party will communicate and provide the necessary elements of the circumstance to the national section of the CMG[191], which will either start direct contacts with the national section of the CMG of the State Party in question[192] or submit the reclamation to the CMG[193]. After that, the CMG will carry on its work based on essentially the same rules as applied for the conflicts between States Parties, in so far as it finds that the reclamation is applicable, and if no final decision is reached the case will be brought before an Arbitration Tribunal which will be constituted for the purpose of resolving the dispute in question.

---

[189] *Ibid.*, Art. 20 (1). The rulings of the Tribunal shall be executed within fifteen days from the notification of the decision (*Ibid.*, Art. 20 (2)). It is also worth mentioning that States Parties declared, through the Protocol of Brasilia, that there is no need for special agreements to recognise the rulings of Arbitration Tribunals created under the Protocol of Brasilia (*Ibid.*, Art. 8).

[190] *Ibid.*, Art. 25.

[191] *Ibid.*, Art. 26.

[192] According with Article 28, Protocol of Brasilia, if there is no agreement during these contacts within fifteen days, the national section of the CMG of the natural person or legal entity which filed the reclamation may bring the case directly to the CMG.

[193] Protocol of Brasilia, Art. 27.

2.3. Current developments

As has been mentioned several times before, the Treaty of Asuncion established a process, not a common market as such. This process, which is seen as a provisional period of negotiations, was due to end by 31 December 1994, when the Common Market of the South would be implemented. At this time, most of the tariff reductions were going to take place, and, more important, a definite institutional structure was going to be created.

For the purpose of setting up a common market by the end of December 1994, Article 18 of the Treaty of Asuncion had said that "[p]rior to the establishment of the common market on 31 December 1994, the States Parties shall convene a special meeting to determine the final institutional structure of the administrative organs of the common market, as well as the specific powers of each organ and its decision-making procedures". In fact a customs union was implemented by 1 January 1995, but a common market-type of integration is due to be reached only at the end of the century.

2.3.1. The Ouro Preto's outcome

On 17 December 1994 the Presidents of the States Parties of the MERCOSUL gathered together, by virtue of Article 18 of the Treaty of Asuncion, and decided upon an Additional Protocol to the Treaty of Asuncion on the Institutional Structure of the MERCOSUL[194], while emphasised the irreversible character of the integration

[194]Hereinafter the "Ouro Preto Protocol" (*Cf.* Art. 52). Published in 34 *ILM* 1244 (1995).

process that would, on 1 January 1995, reach the level of a customs union[195]. In addition to the Ouro Preto Protocol, several other decisions were taken in relation to the implementation of the external common tariff - which eventually came into force on 1 January 1995 - and concerning other sectoral mechanisms necessary for the full operation of the integration process towards the creation of the common market. Probably the most important achievement, at this stage, has been the agreement on a more definite institutional framework for the customs union that started to operate from 1 January 1995. That is why the present Paragraph will give more attention to the setting up of this institutional structure which is also represented in Chart 4, Appendix I, *infra*.

The MERCOSUL is now composed of the Council of the Common Market (CCM), the Common Market Group (CMG), the MERCOSUL Trade Commission (MTC), the Joint Parliamentary Commission (JPC), the Economic-Social Consultative Forum (ESCF), and the MERCOSUL Administrative Secretariat (MAS)[196]. Only the CCM, the CMG and the MTC are intergovernmental organs with decision-making powers[197].

The CCM, which is the highest organ of the MERCOSUL, with responsibility for the political leadership of the process[198], consists of the Ministers of Foreign Affairs - who will co-ordinate its work[199] - and the Ministers of Economy of the

---

[195]Joint Communication of the Presidents of the Countries of the MERCOSUL, of 17 December 1994, para. 12. Not published.
[196]Ouro Preto Protocol, Art. 1.
[197]*Ibid.*, Art. 2.
[198]*Ibid.*, Art. 3.
[199]*Ibid.*, Art. 7.

States Parties[200]. Its Presidency will be on a rotation basis, in alphabetical order, for a period of six months[201].

The CCM will meet at least once every six months, with the participation of the Presidents of the States Parties[202], and is empowered to supervise the implementation of the Treaty of Asuncion, its protocols and agreements signed within its context; to formulate policies and promote measures for the creation of the common market; to assume the legal personality of the MERCOSUL[203]; to negotiate and sign agreements on behalf of the MERCOSUL[204]; to rule on proposals from the CMG; to arrange meetings of ministers; to establish organs when it deems appropriate, and to modify or abolish them; to clarify the substance and scope of its decisions; and to appoint the Director of the MAS.[205] The rulings of the CCM will take the form of Decisions, which are binding upon the States Parties[206].

The CMG, which performs the function of the executive organ of the MERCOSUL[207], consists of four members and four alternates for each country, including representatives of the Ministers of Foreign Affairs, Ministries of Economy or their equivalents, and the Central Banks. The work of the CMG will be co-ordinated by the Ministries of Foreign Affairs.[208]

---

[200]*Ibid.*, Art. 4.
[201]*Ibid.*, Art. 5.
[202]*Ibid.*, Art. 6.
[203]According with Article 34 of the Ouro Preto Protocol, the MERCOSUL shall possess legal personality under international law. Differently from the approach of the Treaty of Asuncion, which did not provide so, the MERCOSUL, from the 1 January 1995, may sign contracts, buy and sell personal and real property, appear in court, hold funds and make transfers (Ouro Preto Protocol, Art. 35), and make headquarters agreements (*Ibid.*, Art. 36).
[204]This function may be delegated to the CMG (Ouro Preto Protocol, Art. 8 (IV), Second part).
[205]Ouro Preto Protocol, Art. 8.
[206]*Ibid.*, Art. 9.
[207]*Ibid.*, Art. 10.
[208]*Ibid.*, Art. 11.

The CMG will hold ordinary and extraordinary meetings, as often as it considers necessary and in accordance with its rules of procedures[209]. When drafting or proposing specific measures to the CCM, the CMG is allowed to call on representatives from other organs of the government or of the institutional structure of the MERCOSUL[210].

The CMG shall have, among others, the following duties and functions: to monitor compliance with the Treaty of Asuncion, its Protocols, and agreements signed within its framework; to propose draft Decisions to the CCM; to take measures to enforce the Decisions of the CCM; to draw up programmes of work designed to ensure the achievement of the common market; to establish, modify or abolish organs, such as working groups and special meetings; to express its views on proposals and recommendations submitted to it by other organs of the MERCOSUL; to negotiate agreements with third countries, when expressly delegated to do so by the CCM; to organise the meetings of the CCM; to prepare reports and studies to the CCM; to choose the Director of the MAS and supervise its activities; and to approve the rules of procedure of the MTC and of the ESCF.[211] The decisions of the CMG are in the form of Resolutions and are binding upon the States Parties[212].

The MTC, which is an assistant organ to the CMG[213], consists of four members and four alternates for each State Party, and is co-ordinated by the Ministries of Foreign Affairs[214]. The MTC will meet at least once a month, or whenever requested to do so by the CMG or by the States Parties[215], and is

---

[209] *Ibid.*, Art. 13.
[210] *Ibid.*, Art. 12.
[211] *Ibid.*, Art. 14.
[212] *Ibid.*, Art. 15.
[213] *Ibid.*, Art. 16.
[214] *Ibid.*, Art. 17.
[215] *Ibid.*, Art. 18.

empowered, *inter alia*, to monitor the application of the common trade policy mechanism both within MERCOSUL and with third countries; to consider and rule upon requests submitted by the State Parties in relation with the application of the common external tariff and other instruments of common trade policy; to take decisions connected with the administration and application of the common external tariff; to report to the CMG on the development and application of the common trade policy instruments, on the consideration of requests received and on the decisions taken with respect to such requests; to propose to the CMG new regulation on trade or changes to the existing legislation; to propose the revision of the tariff rates for specific items of the common external tariff; to create technical committees;[216] and to consider complaints referred to it by the National Sections of the MTC and originated by States Parties or individuals, whether natural or legal persons, in relation with the dispute settlement procedures of the MERCOSUL[217]. The decisions of the MTC have the form of Directives or Proposals. The Directives shall be binding upon the States Parties[218].

The JPC is the organ which represents the Parliaments of the States Parties of the MERCOSUL[219] and is composed of equal numbers of members of Parliament representing the States Parties[220], which are appointed by the respective national Parliament[221]. The JPC is designed to help the acceleration of the implementation of the common rules of the MERCOSUL in the national Parliaments, ensuring prompt and co-ordinated entry into force of the decisions taken by the organs of the

---

[216] *Ibid.*, Art. 19.
[217] *Ibid.*, Art. 21.
[218] *Ibid.*, Art. 20.
[219] *Ibid.*, Art. 22.
[220] *Ibid.*, Art. 23.
[221] *Ibid.*, Art. 24.

MERCOSUL. It will also assist the legal harmonisation process and, when necessary, will be requested by the CCM to examine priority issues.[222]

The ESCF is the organ which represents the economic and social sectors of the States Parties and is composed of equal numbers of representatives from each State Party.[223] Their functions are merely consultative, and are in the form of Recommendations to the CMG[224].

The MAS, with headquarters in Montevideo, provides the operational support for the functioning of the integration process and of the customs union, being also responsible for providing administrative services to the organs of the MERCOSUL.[225] The MAS has, *inter alia*, the following duties: to serve as the official archive of the documentation of the MERCOSUL; to publish and circulate the decisions adopted by the organs of the MERCOSUL, therefore making authentic translations in Spanish and Portuguese of all decisions adopted by the MERCOSUL; to publish the MERCOSUL Official Journal[226]; to organise the meetings of the CCM, the CMG and MTC and, as far as possible, of the other organs; to inform, on a regular basis, the States Parties about the measures taken by each country to incorporate in its legal framework the decisions adopted by the organs of the MERCOSUL; and to bring together national lists of arbitrators and experts, also performing the tasks defined in the Protocol of Brasilia.[227] The MAS will be headed by a Director who is a national of

---

[222] *Ibid.*, Art. 25.
[223] *Ibid.*, Art. 28.
[224] *Ibid.*, Art. 29.
[225] *Ibid.*, Art. 31.
[226] The MERCOSUL Official Journal shall publish the Decisions of the CCM, the Resolutions of the CMG, the Directives of the MTC and the Dispute Settlement Arbitration Rulings, both in Spanish and Portuguese, together with any instrument that is considered relevant either by the CCM or the CMG (Ouro Preto Protocol, Art. 39). It is also worth noting that all decisions of the organs of the MERCOSUL shall be taken by consensus and in the presence of all States Parties (*Ibid.*, Art. 37).
[227] *Ibid.*, Art. 32.

one of the States Parties, chosen by the CMG and appointed by the CCM, on a rotating basis, for a term of two years. He may not be re-elected[228].

In addition to the rules laid down by the Protocol of Brasilia[229], the Ouro Preto Protocol empowered the MERCOSUL Trade Commission to consider complaints to it by the national sections of the MTC and originated by States Parties or individuals, whether natural or legal persons, in relation with the circumstances provided for in Article 1 or 25 of the Protocol of Brasilia.[230]

Further, an Annex to the Ouro Preto Protocol[231] lays down the appropriate rules for complaints initiated in the MTC. The complainant State Party will submit the complaint to the Pro-Tempore Chairman of the MTC, who will include it in the Agenda of the next meeting of the MTC. If there is no decision, the MTC shall pass on the dossier to a Technical Committee.[232] The latter will have thirty days to prepare and submit a joint opinion to the MTC[233].

Taking into account the conclusions of the Technical Committee[234], the MTC will rule on the complaint at its first ordinary meeting following the receipt of the conclusions of the Technical Committee. The MTC may also convene, if it deems appropriate, an extraordinary meeting for the purpose of ruling the complaint.[235] If such meeting does not reach a conclusion, the complaint shall be submitted to the CMG, together with the conclusions of the Technical Committee. The CMG shall,

---

[228] *Ibid.*, Art. 33.
[229] *Cf.* Sub-section 2.2.Paragraph 2.2.2, *supra*.
[230] Ouro Preto Protocol, Art. 21, *caput*. The examination of these complaints by the national section of the MTC does not prevent the complainant State Party from taking action under the Protocol of Brasilia (*Ibid.*, Art. 21 (1)).
[231] Entitled "General Procedure for Complaints to the MERCOSUL Trade Commission". Hereinafter referred to as "Annex to the Ouro Preto Protocol".
[232] Annex to the Ouro Preto Protocol, Art. 2.
[233] *Ibid.*, Art. 3.
[234] Whether or not the Technical Committee has reached a joint opinion (*Ibid.*, Art. 3).
[235] *Ibid.*, Art. 4.

then, give a ruling within thirty days of the receipt by the Pro-Tempore Chairman of the proposals submitted by the MTC[236].

If neither the MTC nor the CMG reach a decision about the complaint, the complainant State may bring the case to the Arbitration procedures, as laid down by Articles 7 to 24 of the Protocol of Brasilia. In this case the MERCOSUL Administrative Secretariat shall be informed accordingly.[237] On the other hand, if there is a ruling, either by the MTC or by the CMG, they must set a reasonable period for the implementation of the respective measures and, if these period expires without the State against which the complaint is made having complied with the provisions of the decisions, the complainant State may address directly the rules of the Protocol of Brasilia which says that the State Party who complains may adopt compensatory measures against the other State which does not comply with the decision.[238]

It is necessary to note, in addition, that the State Party in which the complaint is filed represents the complainant when he is a natural or legal person. In addition, the measures by any ruling has the force of *res judicata* without the need of further implementation.

2.3.2. Towards broader international co-operation

The MERCOSUL, as stated by the Preamble of the Treaty of Asuncion, is an effort to bring about Latin American integration gradually. This is, from the very beginning, the intention of the States Parties of the MERCOSUL. To fulfil this goal the MERCOSUL has worked towards broadening the application of its territory within

---

[236] *Ibid.*, Art. 5.
[237] *Ibid.*, Art. 7.
[238] *Ibid.*, Art. 6.

the American continent and beyond. This last Paragraph of Chapter 1 intends to describe briefly the steps taken towards these aims.

On 19 June 1991, the US and the States Parties of the MERCOSUL signed an Agreement Concerning a Council on Trade and Investment[239]. The main goals of this Agreement are to enhance the spirit of co-operation between the MERCOSUL and the US[240], and develop further international trade and investment relationships among them[241]. This is an additional effort following the launching of the Enterprise for the Americas Initiative, aiming at making closer the relationship between the US and South America[242].

The Agreement on Trade and Investment establishes a Consultative Council on Trade and Investment (CCTI)[243], composed of the representatives of each country[244], with the duty to hold consultations on specific matters related to market opening, trade and investment relations, and the removal of impediments to trade and investment flows[245].

An "Immediate Action Agenda", set up for initiating the work of the CCTI, includes the following minimum list of topics on which consultation should be carried out: co-operation in the Uruguay Round of negotiations; means to facilitate the comprehensive reduction of barriers to trade and investment; policy considerations concerning trade and investment, including access to technology; trade-related aspects of IPRs; export subsidy practices in agriculture; market access for goods and services;

---

[239]Portuguese version published in **Paulo Roberto de Almeida**, note 130, *supra*. English version published in 30 *ILM* 1034 (1991). Hereinafter the "Agreement on Trade and Investment".
[240]Agreement on Trade and Investment, Preamble (1).
[241]*Ibid.*, Preamble, (2).
[242]See, *e.g.*, Agreement on Trade and Investment, Preamble (3), (7), and (8).
[243]Agreement on Trade and Investment, Art. 1.
[244]*Ibid.*, Art. 2. Delegations of the States Parties of the MERCOSUL are represented by the Ministries of Foreign Affairs, and that of the US is represented by the Office of the United States Trade Representative.
[245]*Ibid.*, Art. 5.

sanitary and phytosanitary requirements in agriculture; safeguard regimes; and dumping and subsidies. This list does not preclude the suggestion by any participant of other topics for consultation.

In addition to this initiative the States Parties of the MERCOSUL are pursuing other co-operation programmes with Bolivia and Chile[246], Japan[247], within the framework of the negotiations that has arisen from the Summit of Americas[248], and with the European Union. The latter deserves further consideration.

Following the beginning of the creation of the MERCOSUL, a technical co-operation arrangement between the EC and the MERCOSUL was negotiated. These negotiations concluded with an Agreement on Inter-Institutional Co-operation signed on 29 May 1992[249]. The co-operation instruments provided by this Agreement were basically designed to provide the MERCOSUL with the necessary technical assistance, institutional support, exchange of information, and training of personnel. For this purpose a Joint Consultative Committee was set up. This led for a more substantive discussion on the commercial approximation of the two areas, and to the

---

[246]Which must be seen as an original desire of the States Parties of the MERCOSUL. *Cf.* note 149, *supra*. Brazil has also signed an Agreement for Economic Co-operation with Bolivia, on 27 January 1994 (Published in [1994] 13 *BILA* 192-209), an Agreement for Reciprocal Protection of Investments with Chile, on 22 March 1994 (Published in [1994] 13 *BILA* 210-215), and an Agreement for Economic Co-operation with Venezuela, on 15 July 1994 (Published in [1994] 14 *BILA* 260-265). With Chile, however, negotiations moved faster and during the visit of President Eduardo Frei, of Chile, to Brazil in March 1996, it was confirmed that on 25 July 1996 Chile would sign an agreement establishing a free trade area between with the MERCOSUL. For this information see, *e.g.*, Chile Assina Acordo com o MERCOSUL, *Folha de São Paulo*, 23 March 1996; Chile Entra para o MERCOSUL, *Folha de São Paulo*, 26 March 1996; and Chile Fecha Acordo com o MERCOSUL, *Jornal do Brasil*, 26 March 1996. More recently, Brazilian newspapers have also reported that Venezuela is negotiating an agreement with the MERCOSUL, to be signed by November 1996 (See, *e.g.*, Venezuela Ingressará no MERCOSUL, *Jornal do Brasil*, 21 May 1996, and Acordo da Venezuela com o MERCOSUL Tem Apoio do Brasil, *Folha de São Paulo*, 21 May 1996).

[247]See point 7 of the First Meeting of the Committee of Technical Co-operation of CMG (19-20 November 1992), [1993] 8 *BILA* 55-57, at p. 57.

[248]*Cf.* Section 1, Sub-section 1.3., *supra*.

[249]Published in **Paulo Roberto de Almeida**, note 69, *supra*.

establishment of a programme for the setting up of a free trade zone among the two integrated mechanisms.

On 15 December 1995, the MERCOSUL and the EU agreed upon a more substantive set of rules for co-operation with the signature of the "Landmark Inter-Regional Agreement for Co-operation Between the European Community and its Member States and the Common Market of the South and its States Parties"[250]. Considering commercial approximation as an instrument for economic development, and taking into account the experience which has arisen from the Agreement on Inter-Institutional Co-operation between the EU and the MERCOSUL, the Landmark Agreement affirms in the Preamble that its final goal is the creation of an inter-regional association of political and economic character based on the political co-operation between the parties, and on the progressive and reciprocal liberalisation of trade.[251]

Within this framework, an economic and political dialogue is established[252] aiming at co-operation in the areas of norms for agriculture, foodstuff and industries[253], customs duties[254], statistical data[255], intellectual property[256], energy[257], transport[258], science and technology[259], telecommunications and information

---

[250]Hereinafter the "Landmark Agreement". The text of the agreement used here is a non-published version.
[251]The Landmark Agreement is based on the principle of human rights (Landmark Agreement, Art. 1) and has the subject-matter of strengthening the existing relations between the Parties as a means of preparing the basic conditions for the creation of an Inter-regional Association (*Ibid.*, Art. 2).
[252]Landmark Agreement, Arts. 3 and 5.
[253]*Ibid.*, Art. 6.
[254]*Ibid.*, Art. 7.
[255]*Ibid.*, Art. 8.
[256]*Ibid.*, Art. 9.
[257]*Ibid.*, Art. 13.
[258]*Ibid.*, Art. 14.
[259]*Ibid.*, Art. 15.

technology[260], environmental protection[261], education[262], information and culture[263], and combating the problem of illegal drugs[264].

Its institutional framework is based on three organs: the Co-operation Council[265], the Co-operation Committee[266] and the Sub-Committee of Trade[267]. The Co-operation Council, which is an organ of Ministerial level meeting periodically[268], is composed of representatives of Members of the Council of the European Union, Members of the European Commission, Members of the Council of the Common Market and of the Common Market Group[269]. The Co-operation Council will be lead by a President who will be the representative of the EC and of the MERCOSUL on the basis of rotation[270]. The Co-operation Council is empowered to examine the important problems of implementation of the agreement, deciding upon all bilateral and multilateral questions of common interest[271], and to propose recommendations aiming at the final goal of an Inter-Regional Association[272]. The Co-operation Council is also empowered to decide upon the creation of any other organ within the framework of the Landmark Agreement[273].

The Co-operation Committee is composed of representatives of the European Community and of the MERCOSUL[274], and will convene once a year on a rota basis

---

[260] *Ibid.*, Art. 16.
[261] *Ibid.*, Art. 17.
[262] *Ibid.*, Art. 20.
[263] *Ibid.*, Art. 21.
[264] *Ibid.*, Art. 22.
[265] *Ibid.*, Art. 25.
[266] *Ibid.*, Art. 27 (1).
[267] *Ibid.*, Art. 29 (1).
[268] *Ibid.*, Art. 25 (1).
[269] *Ibid.*, Art. 26 (1).
[270] *Ibid.*, Art. 26 (3).
[271] *Ibid.*, Art. 25 (2).
[272] *Ibid.*, Art. 25 (3).
[273] *Ibid.*, Art. 28.
[274] *Ibid.*, Art. 27 (1).

in Brussels and in one of the States Parties of the MERCOSUL[275]. The President of the Co-operation Committee will be chosen on the basis of rotation between one representative of the European Commission and one representative of the MERCOSUL[276]. The Co-operation Committee is an executive organ which is empowered to support the Co-operation Council to perform its tasks, particularly being empowered to promote the commercial relationship between the Parties of the Landmark Agreement; to exchange opinions about questions of common interest and related to the liberalisation of trade and co-operation; to propose actions to the Co-operation Council aimed at trade liberalisation and intensification of co-operation between the Parties; and to propose actions to the Co-operation Council aiming at the final goal of establishing an Inter-Regional Association[277].

The Sub-committee of trade is composed of representatives of the European Union and of the MERCOSUL[278] and is empowered to ensure compliance with the objectives of the Landmark Agreement[279]. Once a year, the Trade Sub-committee will present to the Co-operation Committee information about the development of its work, as well as proposals aiming at the liberalisation of trade between the Parties[280].

CONCLUSION

The process of commercial, economic and political integration of Latin America, as described in this Chapter, has been essentially a learning process. Most Latin American countries experienced the ambitious task of liberalising trade in a continental basis - the example of the LAFTA - and learned that a detailed set of rules

---

[275] *Ibid.*, Art. 27 (2).
[276] *Ibid.*
[277] *Ibid.*, Art. 27 (5).
[278] *Ibid.*, Art. 29 (2).
[279] *Ibid.*, Art. 29 (1).

and strict deadlines could make the goal of multilateral co-operation a difficult task. It is important to bear in mind, however, that the LAFTA, as a process, was successful and led countries to probe integration issues in more detail. The LAFTA also led to the creation of the LAIA which has, in its own way, supported sub-regional agreements on the liberalisation of trade.

As a result, particularly taking as an example the US initiative to lead the process of formation of a free trade zone with continental dimensions, a growing interest in the region is taking place. The FTAA is feasible and seems to be a positive enterprise towards trade liberalisation in the Western Hemisphere. It is obvious that, considering the broad area of application of the FTAA process, conflicts of interests occur, but they are the necessary mechanism to strengthen the process and to make it possible.

The MERCOSUL, on the other hand, is a process which has been carried out with great care. It is an infant process. One should not expect much from the MERCOSUL in the short term. The transition period determined by the Treaty of Asuncion has proved to be a correct choice. It indeed approximated the four countries politically, economically and commercially and has raised the attention of others, from outside the MERCOSUL. The MERCOSUL is now a reality. In spite of concerns, during this transition period, on the institutional structure and mechanisms for the setting up of an economic integrated area, and the lack of legal personality under international law, the MERCOSUL has grown larger and has been applied effectively.

The outcome of the Ouro Preto Protocol seems to indicate further that the MERCOSUL is here to stay. The Ouro Preto Protocol created a more sophisticated institutional framework as a result of the complexities surrounding the integration

---

[280] *Ibid.*, Art. 29 (3).

process. This institutional framework seems to be a reasonable way to achieve the final goal of a Common Market. It lacks, however, a more precise supranational juridical mechanism.

It is necessary to consider that, despite its historical and cultural similarities, national institutional structures of the countries of the MERCOSUL have their own view of the process. The way this juridical infrastructure will be applied, therefore, is distinct in each country. Decisions upon disputes will certainly take into account national economic and social characteristics. A more definite institutional mechanism to harmonise the juridical approach towards the process is necessary and this will be emphasised further in the discussion in Chapters 3 and 4, on the European Union experience.

It is also important to underline that the legislative process of the MERCOSUL should consider a supranational democratic body which would have popular representation. The MERCOSUL seems to lack, from the very beginning of the process, a more effective participation of the societies of the countries involved in this process. A Parliamentary-type of body is likely to bring the concerns from the nationals of the four countries and from their private sector into the legislative process.

The MERCOSUL should consider therefore broadening its institutional framework to include a juridical body, with the objective of harmonising decisions issued by national courts, and a legislative body, democratically represented, to include the goals of all people of the countries of the MERCOSUL into the legislative process.

The present Chapter wishes to provide the reader with an introductory historical background of the integration process in Latin America, and does so giving

emphasis to the project of the MERCOSUL. Note that, although this part of the thesis has concluded that the MERCOSUL institutional framework lacks some more effective organs, this is only a general conclusion. Further in the present research, a discussion regarding more detailed aspects of the particularities of the negotiations towards common rules for patent protection in the MERCOSUL will take place. Before this happens, however, it is important to introduce generally, in Chapter 2, the trends towards the creation of an international system for patent protection. The discussion that follows in the next Chapter is necessary, in the context of the present thesis, because international negotiations commits and affects both national governments and regional arrangements.

CHAPTER 2
ORIGINS AND DEVELOPMENTS OF INTERNATIONAL PATENT LAW

INTRODUCTION

One of the aspects of a commercial integrated area, which has been carefully considered by several arrangements for regional approximation, is the protection of patents (or IPRs in general) within the geographic area in question, and the territorial application of the rights granted by the State. The European Community has developed a detailed juridical understanding on the subject and has been negotiating, for a long time, a common regime for patent protection in the Common Market[1]. The North American Free Trade Agreement has established an extensive set of rules for intellectual property harmonisation among the three participants[2]. The MERCOSUL has also created a Committee on Intellectual Property, under the auspices of Sub-group 7, on industrial and technological policy, aiming at creating common rules for patent protection[3].

Although a more detailed analysis of patent protection within the MERCOSUL and in the EC will be further discussed throughout the present research, it is necessary to describe, in general words, the attempts to harmonise patent protection on a world-wide basis.

That is why the present Chapter discusses the development of an international system for patent protection, considering last century's agreement on an international convention for the protection of industrial property rights; the creation of an organisation with the tasks of administering the arrangements in the field of IPRs, as

---

[1] See, *e.g.*, Chapters 3 and 4, *infra*.
[2] NAFTA, Chapter 17.
[3] Chapters 1, *supra*, and 5, *infra*.

well as promoting international harmonisation of IPRs; the creation of an international system for co-operation in the field of patent granting procedures; and current developments of international patent negotiations within the World Intellectual Property Organization (WIPO).

Section 2 considers the development of the links between IPRs and international trade, which has reached its highest stage of multilateral understanding with the signature of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as a result of the conclusion of the Uruguay Round of Multilateral Trade Negotiations under GATT. Section 2 considers the existing provisions within the original text of GATT; the US attempt to include in the GATT framework common rules for trade in counterfeit goods; and the TRIPS Agreement, which is considered the most advanced and ambitious international attempt to harmonise IPRs.

The analysis that follows should be understood rather as a preliminary approach to this research as a whole, by providing the readers with the necessary background. Unavoidably, what is happening in the international arena affects both national governments and regional arrangements, making this Chapter necessary as an introduction.

1. ORIGINS AND BACKGROUND

The origins of the word "invention" date back to twenty eight centuries ago, when, during the Roman empire, the meaning of the word was chiefly related to the final product, excluding the notion of an inventive idea for the solution of a technical problem. There is no record that leads one to think that at that time the result of the

inventive activity was protected in some way. According to the historians, the protection of an invention took place, firstly, during the Middle Ages, in 1236, when the Municipal Authority of Bordeaux granted a privilege of fifteen years to "Bonafusus de Sancta Columbia e Companhia", for the process of textile manufacturing and painting. The privileges granted at that time were primarily based on the personal will of the monarch and there was no technical assessment of the degree of inventive activity or industrial application of the invention. Generally, the monarch granted privileges to favour specific sectors of national industries.[4]

The first time that an industrial property privilege appeared to be granted under a more technical approach was in the Venetian Republic, when in 1416 Francesco Petri was granted a monopoly for the construction of twenty four mills that could work without the use of water. There is no information to assess the term of protection granted for this specific creation, but the monopoly was apparently given for a specified period of time; others were prohibited from copying or manufacturing it; and the rights were automatically transmitted to the heirs of the right holder. Apparently, some of the legal requirements and the scope of the rights, as granted at that time, were very similar to the requirements and rights as granted today. Further, during the sixteenth and seventeenth centuries patent privileges were widely used by some European states.

The first patent law enacted for the purpose of regulating patent protection as such was the British Statute of Monopolies of 1623[5]. This legislation was very

---

[4]**Douglas Gabriel Domingues**, Direito Industrial - Patentes, Rio de Janeiro: Companhia Editora Forense (1980), pp. 1-4.

[5]1623 21 Ja. 1, c.3,The Statutes at Large, From the First Year of King James the First to the Tenth Year of the Reign of King William the Third, Volume the Third, London: Printed for Mark Basket,

detailed in essence and eventually influenced the form of the US Patent Act, approved by the US Parliament on 10 April 1790. The latter, for instance, required the patent applicant to affirm that he was the actual inventor. Some degree of disclosure was also required for the purpose of filing a patent application, and the privilege was granted for a period of fourteen years.

1.1. The Paris Convention

During last century, the growing industrial capacity and production of the world has determined the expansion of international commerce, aided by the growth in the economies of England and Wales, Ireland and Scotland which was a result of the "Industrial Revolution". This fact, and also the expansion of international commerce made easier by developments in transport and communication, led national legislatures to realise that one of the very specific characteristics of intellectual property was its ability to transcend national boundaries. National laws started, then, to provide for more specific conditions of industrial property protection considering, in addition, the special case of foreign patent applicants, with provisions on a "national treatment-type" of approach. Even so, a holder of an intellectual property right was dependent mainly on reciprocity between the laws of his own country, and those of the country in which he desired to obtain protection. This proved to be an unsatisfactory position, because of the many fundamental differences between the laws of different countries.

At the international level, further attempts took place aiming at a solution to the problem by including in treaties of "friendship, trade and navigation" clauses

---

Printer to the King's Moft Excellent Majesty, and by the Assigns of Robert Basket; And by Henry Woodfall and William Strahan, Law Printers to the King's Most Excellent Majesty.

relating to the protection of industrial property[6]. The contrast between the different national systems of industrial property protection confirmed that the establishment of common principles, and a minimum level of standardisation of industrial property legislation, was unequivocally necessary for further co-operation in this field, in so far as the clauses included in such treaties did not work at all as a solution to the specific circumstances of a foreign applicant.

In 1873, on the initiative of the Austrian-Hungarian government, the first international gathering to study modern industrial property issues took place in Vienna. Though this first congress did not reach any successful conclusion, in 1878, during the Universal Exposition, a second version of this gathering (known as the Trocadero Congress) took place in Paris to discuss in more detail some forms of co-operation mechanisms for a multilateral arrangement in the field of industrial property. Therewith, a Permanent Committee was created and empowered to draft a proposed text for an agreement, following the recommendations that were placed by the participants of the Trocadero Congress. In 1880 the participants of the congress met again in Paris to consider the proposed text of the Permanent Committee, which had been previously distributed to the interested countries. It was further decided to adopt a proposed agreement which was, once again, submitted to the governments of the participating countries.[7]

On 6 March 1883 a Diplomatic Conference was convened and adopted, on 20 March 1883, the text of the International Convention for the Protection of Industrial

---

[6] **João da Gama Cerqueira**, Tratado da Propriedade Industrial, V. II, Tomo II, Parte III, Rio de Janeiro: Revista Forense (1956), p. 408.
[7] *Ibid.*, pp. 409-410.

Property (the Paris Convention)[8] which established a "... Union for the protection of industrial property"[9]. The necessity to adapt the text of the Paris Convention to the development of new technologies and needs of modern society has required the original text of the Paris Convention to be revised and amended six times: at Brussels, on 14 December 1900; at Washington, on 2 June 1911; at The Hague, on 6 November 1925; at London, on 2 June 1934; at Lisbon, on 31 October 1958; at Stockholm, on 14 July 1967; and as amended on 2 October 1979[10].

Considering industrial property in a broad sense, the Paris Convention protects patents (including patents of importation, patents of improvement, patents and certificates of addition)[11], utility models, industrial designs, trade-marks, service marks, trade names, indications of source or appellation of origin, and the repression of unfair competition[12]. Industrial property protection shall apply additionally to the

---

[8]The signatory States were Belgium, Brazil, France, Guatemala, Italy, the Netherlands, Portugal, San Salvador, Serbia, Spain, and Switzerland. As at 1 January 1996, the Paris Convention had 136 Contracting Parties. Some had signed and ratified all the revisions, up to the 1967 Stockholm revision, while others are Parties of past revisions only. See, *e.g.*, WIPO Doc. N. 423 (E) (1 January 1996) States Party to the Convention Establishing the World Intellectual Property Organization (WIPO) and/or Other Treaties Administered by WIPO and/or to the International Convention for the Protection of New Varieties of Plants (UPOV) - Governing Bodies of WIPO, of the Unions Administered by WIPO and their (Permanent) Committees, and of the Rome Convention, Status on January 1, 1996.

[9]Paris Convention, Art. 1 (1). In 1883 the agreement on the Paris Convention created a Union which was to be administered by an International Bureau (the Paris Union). Then, in 1883, another International Bureau was created to administer the Berne Union, established by the Berne Convention for the Protection of Literary and Artistic Works (the Berne Convention). The two International Bureau were united, institutionally and administratively, in 1893, being named, in French, *Bureaux Internationaux Réunis pour la Protection de la Proprieté Intellectuelle* (translated into English as the United International Bureau for the Protection of Intellectual Property) which led to the famous acronym BIRPI. This was later replaced by another International Bureau administered by WIPO, as it will be seen in Sub-section 1.2, *supra*.

[10]**BIRPI**, Paris Convention for the Protection of Industrial Property, Geneva: BIRPI (1968). When the present research refers to the Paris Convention it means the text of the latest revision at Stockholm in 1967.

[11]Paris Convention, Art. 1 (4).

[12]*Ibid.*, Art. 1 (2).

fields of commerce and industry, to agricultural and extractive industries, and to all manufactures or natural products[13] .

The main aspiration of the Paris Convention is to set two general and essential principles related to the international character of industrial property rights, as above described. These two principles, which will be observed in more detail below in Paragraph 1.1.2, are the greatest achievement of the Paris Convention.

1.1.1. Institutional framework

The administrative functions of the Paris Convention are performed by the International Bureau[14] which has the following functions: to act as the secretariat of the various organs of the Paris Union[15]; to assemble and publish, through a monthly periodical[16], information concerning the protection of industrial property[17]; and to conduct studies, or provide services, aiming at facilitating the protection of industrial property[18]. The chief executive of the Paris Union is the Director General of WIPO who will represent the Union internally and externally[19].

---

[13] *Ibid.*, Art. 1 (3).
[14] *Ibid.*, Art. 15 (1) (a). Further details on the nature of the International Bureau of Intellectual Property (BIRPI), replaced by the International Bureau of the WIPO in 1967, will be provided below, in Sub-section 1.2. As the text of the Paris Convention which is used as a reference here is the one revised at Stockholm in 1967, this Chapter will refer always to the International Bureau of WIPO.
[15] *Ibid.*, Art. 15 (1) (b).
[16] *Ibid.*, Art. 15 (3).
[17] *Ibid.*, Art. 15 (2). This provision also establishes that Members of the Union are requested to communicate promptly all new laws and official texts, as well as any information or publication which may be useful for the International Bureau of the WIPO, concerning the protection of industrial property. All information kept by the International Bureau of the WIPO, shall, on request, be provided to any country Member of the Union.
[18] *Ibid.*, Art. 15 (5).
[19] *Ibid.*, Art. 15 (1) (c).

The Paris Union has an Assembly consisting of the countries of the Union which are bound by Articles 13 to 17 of the Paris Convention[20]. The government of each country will be represented by one delegate, who may be assisted by alternate delegates, advisors and experts[21]. Each country member of the Paris Union shall have only one vote[22]. The Assembly is empowered to deal with all matters relating to the maintenance and the development of the Union; to give directions for the preparation for conferences of revisions; to review and approve reports and activities of the Director General of WIPO and of the Executive Committee; to elect members of the Executive Committee of the Assembly; to establish committees of experts and working groups; and to determine which countries or international organisations may attend the meetings of the Assembly as observers[23].

The quorum for decisions shall be of at least one half of the countries members of the Assembly[24]. The Assembly may, nevertheless, make decisions with the presence of one-third or more countries members, in so far as these decisions do not relate to the Assembly's own procedures. In this case, the International Bureau of the WIPO shall communicate the decisions taken under this condition to the countries members of the Assembly which were not represented at the meeting, asking them to express, in writing, their vote or abstention within a period of three months from the date of communication. The decisions in question will take effect only provided that the number of countries which expressed their votes in writing reaches the minimum

---

[20] *Ibid.*, Art. 13 (1) (a).
[21] *Ibid.*, Art. 13 (1) (b).
[22] *Ibid.*, Art. 13 (4) (a).
[23] *Ibid.*, Art. 13 (2) (a). By virtue of Article 15 (6), Paris Convention, the Director General of the WIPO and any staff member designated by him may participate, without the right to vote, in all meetings of the Assembly, of the Executive Committee, and of any other committee of experts or working group.

quorum of one-half of the members of the Assembly.[25] With the exceptions of decisions regarding amendments to Articles 13 to 17, which require three quarters of the votes cast[26], the decisions of the Assembly may be taken with a minimum of two-thirds of the votes cast[27]. Abstentions will not be considered as votes[28].

The Assembly shall meet at least once in every third calendar year upon convocation by the Director General of WIPO[29], and may be requested to meet in extraordinary sessions upon convocation from the Director General or at the request of one quarter of the countries who are members of the Assembly[30].

The Assembly of the Paris Union has an Executive Committee, composed of elected countries members of the Assembly[31], as of one-fourth of the member countries of the Assembly[32]. One representative of each country member of the Executive Committee shall be appointed by the government in question and shall be represented by only one delegate, who may be assisted by alternate delegates, advisors, and experts[33]. Members may be re-elected , but only to a maximum of two-thirds of such members[34]. Meetings of the Executive Committee shall take place once

---

[24]*Ibid.*, Art. 13 (4) (b).
[25]*Ibid.*, Art. 13 (4) (c).
[26]*Ibid.*, Art. 17 (2). Articles 13 and 17 (2) of the Paris Convention, however, require a minimum of four-fifths of the votes cast to be amended (*Ibid.*). Amendments may be initiated by any country member of the Paris Union, the Executive Committee, or by the Director General of WIPO. Proposals of amendments shall, nevertheless, be communicated to the member countries by the Director General of WIPO at least six months before being considered by the Assembly (*Ibid.*, Art. 17 (1)).
[27]*Ibid.*, Art. 13 (4) (e).
[28]*Ibid.*, Art. 13 (4) (e).
[29]*Ibid.*, Art. 13 (7) (a).
[30]*Ibid.*, Art. 13 (7) (b).
[31]*Ibid.*, Art. 14 (2) (a). Members of the Executive Committee are elected by the Assembly (Art. 13 (2) (a) (iv)), who shall consider the equitable geographical distribution of the members of the Executive Committee (*Ibid.*, Art. 14 (3)).
[32]*Ibid.*, Art. 14 (3).
[33]*Ibid.*, Art. 14 (2) (b).
[34]*Ibid.*, Art. 14 (5) (b). Rules governing election of members of the Committee and possible re-election shall be established by the Assembly (*Ibid.*, Art. 14 (5) (c)).

a year, in ordinary session by convocation of the Director General of the WIPO[35], and, in extraordinary session, either upon convocation of the Director General of the WIPO or at request of its chairman or of one quarter of its members[36].

The Executive Committee has the following functions: to prepare the draft agenda of the Assembly; to submit proposals to the Assembly in which regards to the draft programme, triennial budget and periodical reports of the Director General of WIPO; to approve the specific yearly budgets and programmes prepared by the Director General; and to take all necessary steps to ensure the execution of the programme of the Union.[37]

1.1.2. The national treatment principle and the right of priority

As has been mentioned before, the Paris Convention relies on two basic principles which are the pillars of the international patent system. Both principles were introduced by the Paris Convention and became quite well known during negotiations of other multilateral arrangements in the field of IPRs.

The Paris Convention has, therefore, instituted that "[n]ationals of any country of the Union shall, ..., enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; ...", and that, as a consequence, "... they [foreign applicants] shall have the same protection as the latter [the national applicant], and the same legal remedy against any infringement of their rights ..."[38].

---

[35]*Ibid.*, Art. 14 (7) (a).
[36]*Ibid.*, Art. 14 (7) (b).
[37]*Ibid.*, Art. 14 (6) (a). See, also, Chart 1, Appendix II, *infra*, for a more detailed view about the institutional structure of the Paris Union.
[38]*Ibid.*, Art. 2 (1).

This principle is a very forthright rule that leaves little space for further interpretation which could run against the main goals of the Paris system. In addition to that, Article 3 of the Paris Convention affirms also that nationals of countries which are not members of the Union shall benefit from the application of the "national treatment" principle, if they are domiciled or have real and effective industrial or commercial establishment in the territory of one of the countries members.

In accordance with the studies carried out by Gama Cerqueira[39], the operation of the national treatment principle provides for two methods of application. Firstly, the principle of assimilation which includes the acquisition of industrial property rights; the duration and scope of these rights, as well as the obligations imposed for its permanence as a legal right; the legal measures for the protection of the rights; and the civil and penal sanctions available in national laws against the infringement of intellectual property rights.

Secondly, Gama Cerqueira refers to the "unionist treatment" of the principle which includes the object of the following Articles of the Paris Convention: 4 (right of priority), 4*bis* (independence of patents), 5 (working requirements of the patent and compulsory license), 5*bis* (grace period), 6 (conditions of registration of marks), 6*bis* (well-known marks), 6*ter* (State emblems, official hallmarks and emblems of intergovernmental organisations), 7 (nature of goods to which a trademark is applied), 8 (trade names), 10 (false indications) and 10*bis* (unfair competition).

In accordance with the thoughts of Gama Cerqueira, the "unionist treatment" forms the basis of the application of the right of priority principle. Taking into account that the novelty of an invention is a condition *sine qua non* for the granting of a patent

privilege, the fact that an invention has been disclosed as a consequence of the filing of a patent application in another country could lead to the understanding that the invention is already part of the prior art, thus not patentable. The discussions that led to the signature of the Paris Convention had a major concern with this field and a solution was necessary to be found. One possible solution was the creation of a simultaneous filing system, which would be done, firstly, before national patent offices and, then, in the consulates of the other countries in which the inventor desired to obtain protection. This solution was, for obvious reasons, considered difficult in practice.[40]

The discussions that followed led to the development of the right of priority principle, which is, in a strict sense, an exception to the novelty requirement. This principle primarily rules that once the inventor has filed a patent application in his country - or in any other country of the Union - he is given an extra period of twelve months[41] to apply for patent protection in other countries of the Union, without his invention being considered as part of the prior art, and, thereupon, not patentable.

An inventor who wishes to enjoy the benefit of the right of priority shall be required to make a declaration indicating the date of the first filing and the country in which the application was filed[42]. The countries of the Union may require further formalities. The inventor, for instance, may be requested to produce a copy of the application previously filed. The copy of the application, certified as correct by the authority which received it, shall not require any authentication. Contracting Parties

---

[39]Note 6, *supra*, p. 421.
[40]**João da Gama Cerqueira**, note 6, *supra*, p. 423.
[41]Paris Convention, Art. 4 (C) (1).
[42]*Ibid.*, Art. 4 (D) (1). This information will be mentioned in the national publication issued by the competent authority (*Ibid.*, Art. 4 (D) (2)).

may require, however, the application to be accompanied by a certificate from the same authority showing the date of filing, and by a translation[43]. If necessary, for the purpose of fulfilling the requirements of the law, members may require, thereafter, further proof of a previous application[44].

Members of the Union may not refuse a priority, or a patent application on the ground that the applicant claims multiple priorities, even if those originate in different countries. Neither may a member of the Paris Union refuse a priority on the ground that an application claiming one or more priorities contains one or more elements which were not described in a previous application[45]. If the examination finds that an application for a patent contains more than one invention, the applicant is allowed to divide the application into several applications, and claim priority from the date of the initial application for each[46].

1.2. The creation of the WIPO

The World Intellectual Property Organization (WIPO) is the successor of the BIRPI[47]. As the growing necessity for a more effective institutional mechanism to administer the Paris and Berne Unions, and their special agreements, became manifest, members of both Unions started to carry out modifications to their institutional structures as soon as 1948, when the Brussels Revision Conference of the Berne Union created a Permanent Committee of the Berne Union[48].

---

[43] *Ibid.*, Art. 4 (D) (3).
[44] *Ibid.*, Art. 4 (D) (5).
[45] *Ibid.*, Art. 4 (F).
[46] *Ibid.*, Art. 4 (G) (1).
[47] *Cf.* note 9, *supra*.
[48] **Arpad Bogsch**, Brief History of the First 25 Years of the World Intellectual Property Organization, Geneva: WIPO (1992), p. 9.

Then, according to Arpad Bogsch, the idea for the setting up of a more centralised institutional framework to administer the Paris and Berne Conventions, and its special agreements, was developed and translated into practical proposals in 1962. From 1963 up to 1967 the idea was further elaborated and it was included in the negotiations of the 1967 Stockholm Conference.[49]

The Conference of the Parties gathered in Stockholm to negotiate two major changes in the framework of Paris and Berne Unions, as well as on the five special agreements under the Paris Union[50]. The first point of discussion was the implementation of a structural and administrative reform of the Unions; the second, some modification in the substantive provisions of Paris and Berne Conventions. With the participation of seventy three States and thirty six organisations, the Stockholm Conference lasted for more than a month, from 11 June to 14 July 1967, and concluded successfully the revision of seven multilateral treaties and the establishment of a new one: the Convention Establishing the World Intellectual Property Organization[51].[52]

The WIPO was established to promote the protection of intellectual property throughout the world with a view to enhance co-operation among States, and to

---

[49]*Ibid.*, pp. 9-10.

[50]The agreements are: the Madrid Agreement Concerning the International Registration of Marks, concluded in 1891; the Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods, also concluded in 1891; the Hague Agreement Concerning the International Deposit of Industrial Designs, concluded in 1925; the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks, concluded in 1957; and the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration, concluded in 1958.

[51]Hereinafter the "WIPO Convention". The WIPO Convention came into effect on 26 April 1970. Eventually, the WIPO, whose headquarters are in Geneva (WIPO Convention, Art. 10 (1)), became a Specialised Agency of the United Nations on 17 December 1974. The WIPO Convention is published in 6 *ILM* 782 (1967).

[52]**Arpad Bogsch**, note 48, *supra*, p. 11.

ensure administrative co-operation among the Unions.[53] This was to be done through the following actions: to promote the development of measures to facilitate the efficient protection of intellectual property and to ensure the harmonisation of national laws in this area; to perform administrative tasks for the Paris, Berne and Special Unions; to encourage the conclusion of other international agreements in the field of intellectual property; to offer services of technical co-operation to States which would eventually require legal assistance; to gather together and disseminate information about IPRs; and to provide services facilitating the international protection of IPRs, and, where appropriate, provide for registration services and the publication of data concerning those registrations[54].

The institutional framework of the WIPO, which was probably the main goal of the Stockholm Conference, consists of a General Assembly[55], the Conference of the Parties, and the Coordination Committee.

The General Assembly consists of the State Parties of the WIPO Convention which are also members of the Unions[56], represented by one delegate, who may be assisted by alternate delegates, advisors, and experts[57]. The functions of the General Assembly are to appoint the Director General of WIPO, upon nomination by the Coordination Committee[58]; to review and approve reports of the Director General, as well as measures proposed by the latter, and the activities of the Coordination

---

[53]WIPO Convention, Art. 3.
[54]*Ibid.*, Art. 4.
[55]It is worth noting that each of the Unions (Paris, Berne, Madrid, Hague, Nice and Lisbon) has an Assembly, but not a General Assembly that is part only of the institutional framework of the WIPO. *Cf.* Appendix II, Chart 1, *infra*.
[56]WIPO Convention, Art. 6 (1) (a).
[57]*Ibid.*, Art. 6 (1) (b). By virtue of Article 6 (3) (a), each State shall have only one vote in the General Assembly.

Committee; to adopt the triennial budget and financial regulations; and to determine which States not Members of the WIPO, or inter-governmental organisations, may be admitted as observers in its meetings. The General Assembly shall meet once in every third calendar year in ordinary session, upon convocation by the Director General[59], and in extraordinary session upon convocation by the Director General, at the request of the Coordination Committee or at the request of one quarter of the States members of the General Assembly[60]. With regard to the quorum for convening the General Assembly and the quorum for taking decisions, there are applied the same rules as those described for the Paris Convention, in Sub-section 1.1, *supra*.

The Conference consists of the States Parties of the WIPO Convention whether or not they are members of the Unions[61]. The functions of the Conference are the following: to discuss matters in the field of intellectual property and to adopt recommendations to such matters; to adopt the triennial budget and to establish the triennial programme of legal-technical assistance; to adopt amendments to the WIPO Convention; and to determine which States not members of the WIPO, and which inter-governmental and international non-governmental organisations, may be admitted as observers to its meetings[62]. The Conference shall meet in ordinary session, upon convocation by the Director General, during the same period and at the same place as the General Assembly[63]; and in extraordinary session, upon convocation by the Director General, at the request of the majority of the Member States of the

---

[58]WIPO Convention, Art. 8 (3) (v). The Director General shall be appointed for a term of at least six years and he may be re-appointed (*Ibid.*, Art. 9 (3)).
[59]*Ibid.*, Art. 6 (4) (a).
[60]*Ibid.*, Art. 6 (4) (b).
[61]*Ibid.*, Art. 7 (1).
[62]*Ibid.*, Art. 7 (2).
[63]*Ibid.*, Art. 7 (4) (a).

WIPO Convention[64]. Again, the same rules for quorum and decision-making, as those provided by the Paris Convention, in Sub-section 1.1, *supra*, apply to the Conference.

The Coordination Committee of WIPO is composed of the States Parties of the WIPO Convention who are members of the Executive Committee of the Paris or Berne Unions, being a number of more than one quarter of the number of the countries members of the Assembly which elected it. The Executive Committees of the Unions will then indicate which members will be designated to participate in the Coordination Committee[65]. The latter has the following functions: to give advice to the organs of the Unions, the General Assembly, the Conference, and the Director General, on all administrative, financial and other matters; to prepare the draft agenda of the General Assembly, and the draft agenda and draft programme of the Conference; to establish annual budgets and programmes, on the basis of the triennial budget of expenses of the Unions and of the Conference; to nominate the Director General for appointment; and to appoint the Acting Director General, in case the post becomes vacant between two sessions of the General Assembly[66].

The Co-ordination Committee meets once a year in ordinary session, upon convocation by the Director General of the WIPO - generally at the headquarters of the WIPO[67] - and, in extraordinary session, either upon convocation by the Director General, upon the own initiative of the Co-ordination Committee, or at the request of its Chairman or one quarter of its members[68].

---

[64] *Ibid.*, Art. 7 (4) (b).
[65] *Ibid.*, Art. 8 (1) (a).
[66] *Ibid.*, Art. 8 (3).
[67] *Ibid.*, Art. 8 (4) (a).
[68] *Ibid.*, Art. 8 (4) (b).

The secretariat services offered by the WIPO will be carried out through the International Bureau of Intellectual Property (the International Bureau)[69]. The latter is headed by the Director General of WIPO, assisted by two or more Deputy Directors[70]. The Director General is also the chief executive of the WIPO, empowered to represent the organisation, and to report to the General Assembly as to the internal and external affairs of the WIPO.[71] The Director General shall also prepare the draft programmes, budgets[72] and periodical reports on activities which will be distributed to the governments, the competent organs of the Unions and the organs of the WIPO[73].[74]

Membership to the WIPO is opened to any State which is a member of the Unions administered by WIPO; to any member of the United Nations, or its Specialised Agencies; to members of the International Atomic Energy Agency; to any party to the Statute of the International Court of Justice; or to any other State which is invited by the General Assembly to become Party to the WIPO Convention.[75] Countries wishing to adhere to the WIPO Convention must sign it, ratify it, and deposit the instrument of ratification with the Director General of WIPO[76].

---

[69]*Ibid.*, Art. 9 (1).
[70]*Ibid.*, Art. 9 (2).
[71]*Ibid.*, Art. 9 (4).
[72]When drafting up the budget the Director General shall take into account two separate budgets: (a) the budget of expenses to the Unions, which includes provision for expenses of interest to the several Unions; and (b) the budget of the Conference, which includes provision for the expenses related with holding sessions of the Conference and for the cost of the legal-technical assistance programme (WIPO Convention, Art. 11).
[73]WIPO Convention., Art. 9 (5).
[74]For a better view on the institutional structure of the WIPO and its relationship with the other Unions, see Chart 1, Appendix II, *infra*.
[75]*Ibid.*, Art. 5. As at 1 January 1996, the WIPO had 157 States Parties (WIPO Doc. N. 423 (E), note 8, *supra*).
[76]*Ibid.*, Art. 14. By virtue of Article 16 of WIPO Convention reservations are not allowed.

1.3. Mentioning the setting up of a patent co-operation system

From 1967 up to 1970 sixteen preparatory meetings, organised by the International Bureau, took place in order to draft an international agreement to harmonise and facilitate the procedures to file a patent application, in a single form, which would be valid in several countries. On 19 June 1970, the Diplomatic Conference convened to decide upon an international system for patent filing procedures concluded its work, adopting the Patent Cooperation Treaty (PCT), and its Regulations[77].

The PCT system makes the filing of a patent application in many countries easier by providing mechanisms in which a patent applicant would file a single application[78], designating the Contracting State or States of the PCT[79] in which he desires to obtain protection[80]. National patent offices will operate as "receiving offices", checking and processing the application[81]. One copy of the application is kept by the receiving office (home copy), another copy will be transmitted to the International Bureau (record copy)[82], and a further one will be sent to the

---

[77]The ratification process of the PCT was very slow for several reasons. In particular, because of the resistance of many patent agents fearing that their services would become needless as a result of the PCT system. Another reason was that some Western European countries intended to have the PCT in operation only after the European Patent Convention would be fully established and operating. The PCT came into force, finally, on 1 June 1978 (**Arpad Bogsch**, note 48, *supra*, p. 24). The text of the PCT, with Regulations, is published in 9 *ILM* 978 (1970).

[78]Called "international application" if filed under the PCT system (PCT, Art. 2 (vii)). It is noteworthy that under Rule 13.1, Regulations of the PCT, an international application "... shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')".

[79]On 1 January 1996, the PCT had eighty three Contracting Parties (WIPO Doc. N. 423 (E), note 8, *supra*).

[80]PCT, Art. 4 (ii).

[81]*Ibid.*, Art. 10.

[82]The record copy is the one which will be considered the true copy of the international application (PCT, Art. 12 (2)). If the International Bureau does not receive such a copy within a specified period of time, the international application will be considered withdrawn (*Ibid.*, Art. 12 (3)).

International Searching Authority[83].[84] The International Searching Authority will then carry out the international search and endeavor to discover as much as the "relevant prior art"[85] as its facilities permit, on the basis of the claims, with due regard to the description and the drawings (if any)[86]. After that, the International Searching Authority will establish an international search report[87], which shall be transmitted to the International Bureau and to the applicant[88].

The PCT system offers another mechanism to the applicant, in which he may submit his international application to an international preliminary examination[89], indicating the Contracting State or States in which he intends to use the results of his international preliminary examination[90]. The main purpose of an international preliminary examination - which will be carried out by an International Preliminary

---

[83]Being appointed by the Assembly of the PCT Union (PCT, Art. 16 (3)(a)), for a fixed term (*Ibid.*, Art. 16 (3)(d)), the International Searching Authority may be either a national office or an inter-governmental organisation with the task of, *inter alia*, writing up of documentary search reports on prior art with respect to inventions (*Ibid.*, Art. 16 (1)). According with Rule 36, of the PCT Regulations, there are three minimum requirements to become an International Search Authority: the national office or inter-governmental organisation must have at least 100 full-time employees with sufficient technical qualifications to carry out searches; the office or organisation must possess at least the minimum documentation which will enable them to assess the relevant prior art; and the office or organisation must have staff who are capable of searching the required technical fields and who have the language facilities to understand at least those languages in which the minimum documentation is written or translated.

[84]PCT, Art. 12 (1).

[85]Rule 33.1 (a), Regulations of the PCT, determines that the "'relevant prior art' shall consist of everything which has been made available to the public anywhere in the world by means of written disclosure (...) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (...), provided that the making available to the public occurred prior to the international filing date". If the "... written disclosure refers to an oral disclosure, use, exhibition, or other means, whereby the contents of the written disclosure were made available to the public, ..." before the filing of the international application, the report on the international search must mention such fact and the date when it occurred (Rule 33.1. (b), Regulations of the PCT).

[86]PCT, Art. 15.

[87]*Ibid.*, Art. 18 (1).

[88]*Ibid.*, Art. 18 (2).

[89]Adhering States to the PCT are not obliged to accede to the international preliminary examination system, being, thus, not bound by the provisions of Chapter II of the PCT (PCT, Art. 64).

[90]PCT, Art. 31.

Examining Authority[91] - is to formulate a preliminary and non-binding opinion on the satisfaction of the basic criteria of novelty, inventiveness and industrial application[92]. The outcome of this preliminary search is an International Preliminary Examination Report which states whether the claim appears to satisfy the criteria of novelty, inventive step and industrial application. This report shall not contain any statement as regards the patentability or non-patentability of the invention.[93]

To sum up, the PCT system provides eligible applicants[94] with at least three advantages. First, and probably the main one, is the timing advantage it gives as to the payment of fees, and incurring of translation costs. Second, a patent applicant may apply for a patent in several countries using a single procedure. Third, the patent applicant has the possibility of having a technical assessment on the patentability or non-patentability of his invention, before he starts to incur higher costs for applying for patent protection. This undoubtedly makes patent filing procedures much simpler, and, above all, less costly.

1.4. The efforts towards a Patent Harmonization Treaty: the PLT

Since 1983, preparatory work led by the WIPO has approached the creation of a "Treaty Supplementing the Paris Convention as far as Patents are Concerned", the Patent Law Treaty (PLT). This treaty was initially called the "Treaty on the Harmonisation of Patent Law" The preparatory work, initially designed to introduce

---

[91]Rule 63 sets up the minimum requirements to be an International Preliminary Searching Authority, which are literally the same of those of the International Searching Authority, as provided in note 83, *supra*.
[92]PCT, Art. 33.
[93]*Ibid.*, Art. 35 (2).

an international novelty grace period from the priority date[95], has dealt also with the issues on disclosures and descriptions, claims, unity of invention, priority, rights conferred by a patent and obligations of the right holder, conditions of patentability, prior art effects, term of patent protection, enforcement of patent rights, and reversal of the burden of proof[96].

The most important, and probably most controversial, point of discussion during the first diplomatic conference has been the establishment of a grace period system. Also, the discussions on the exclusion of the first-to-invent principle - against the inclusion of the widely recognised first-to-file principle - from the PLT system raised concerns from the delegation of the US. The latter regards the first-to-invent system as a more efficient and fair system for patent applicants, in so far as the inventor may publish, use and test his creation commercially before having to bear the high costs of patent filing procedures and the maintenance of a patent right. After testing his creation, the inventor could decide whether his invention is worth patenting or not, without having any risk with regard to the non-patentability of his invention on grounds of lack of novelty.

Other discussions have occurred in different areas of substantive patent law, such as the basic criteria for patentability, term of protection and enforcement issues. The First Part of the Diplomatic Conference, held in 1991, could not, however,

---

[94]Those who are nationals of a Contracting State, or a legal entity of a Contracting State, or those which are nationals or residents of a country member of the Paris Union, allowed by the Assembly to file international applications under the PCT system (PCT, Art. 9).

[95]**Heinz Bardehle**, WIPO Patent Harmonization: a Time for Compromise, [1991] 5 *World Intellectual Property Report* 95-99, at p. 95.

[96]As in the draft treaty presented to the First Part of the Diplomatic Conference that took place at The Hague, from 3 to 21 June 1991 and published in **WIPO**, Records of the Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as far as Patents are Concerned - Volume I: First Part of the Diplomatic Conference, The Hague, 1991, Geneva: WIPO (1991).

conclude its work because of two basic reasons. Firstly, the Uruguay Round of Multilateral Trade Negotiations of the GATT had not, at that time, been completed, and delegations feared that some duplication of work could occur. Secondly, the US had repeatedly affirmed that consultations with the interested circles in their country had not been conclusive and that they needed some more time[97].

Subsequently, from 8 to 12 May 1995, a Consultative Meeting for the Preparation of the Second Part of the Diplomatic Conference for the Conclusion of the Patent Law Treaty, was due to take place[98].

Although the PLT appears to be a duplication of the provisions of the TRIPS Agreement, in my opinion this assertion is based on a superficial examination of the circumstances as a whole. The negotiations towards the PLT occur under the auspices of the WIPO, which is the appropriate forum for international intellectual property discussion. A future Patent Law Treaty has the opportunity to play a determinant part in fulfilling the gaps left by the TRIPS Agreement, such as the environmental-related aspects of patent rights; biotechnology; harmonised rules for patent granting procedures; the recognition of the existing technological gaps between developing and developed world; and, obviously, a grace period system with international application. The PLT must be seen rather as a development of the international patent system that has started more than one-hundred years ago than as a duplication of the outcome of the negotiations taken under the GATT auspices. Even if it does not reach a successful end, the history of negotiations will probably be a very useful source for substantive patent laws and practices.

---

[97] **Arpad Bogsch**, note 48, *supra*, p. 37.
[98] This information was extracted from [1995] 2 *EIPR* D-56.

2. PATENTS AND INTERNATIONAL TRADE

Before getting on to the issues on intellectual property and international trade, it is necessary to provide a brief historical view of the setting up of the world trade system. The origins of the General Agreement on Tariffs and Trade (GATT) date back to 24 March 1948, when fifty two states signed, in Cuba, the Havana Charter, aiming at setting up rules to regulate and encourage the liberalisation of international trade, and wishing to create an International Trade Organisation (ITO). Ironically enough, the initiative to establish such an organisation was taken by the US and the most important reason for the ITO's failure was that the US Congress did not approve the so-called "ITO Charter"[99]. The GATT is itself an international agreement that, because of the historical events which occurred during the attempt at establishing the ITO, has the status of an international binding agreement, and the functions of a multilateral trade organisation.[100]

---

[99]Some argue that, because of the reluctance of the US Congress to ratify the Havana Charter, the latter was never submitted by the US government to Congress. See, *e.g.*, **Rüdiger Wolfrum & Christiane Philipp** (ed.), United Nations: Law, Policies and Practice, London: Martinus Nijhoff Publishers (1995), V. I, p. 532. It appears that this information is not accurate, because in Public Papers of the President of the United States, Harry S. Truman - January 1 to December 31, 1949, Washington, DC: United States Government Printing Office (1964), pp. 233-235, it is published the "Special Message to the Congress Transmitting the Charter for the International Trade Organization", of 28 April 1949. At the end of the messsage, page 235, a note says that "Congress did not authorize the United States to accept membership in the International Trade Organization". No mention is made of the fact that President Truman withdrew the Havana Charter on grounds of Congress' reluctance to approve it. Apparently, what happened is that the US Congress did not accept membership in the ITO, and, following this event, President Truman decided not to resubmit the Havana Charter to the Congress. See, for instance, **GATT**, Analytical Index: Guide to GATT Law and Practice, Geneva: GATT (1994), 6th ed, p. 6, note 7.

[100]See, also, **John H. Jackson**, The World Trading System: Law and Policy of International Economic Relations, Massachusetts: The MIT Press (1989).

Since its troublesome birth in 1948, the world trade system has operated under the GATT 1947 framework on a provisional basis[101], and has been revised by several rounds of multilateral trade negotiations[102]. The last round of negotiations, the Uruguay Round, was conceived in order to approach several issues that were not included in the GATT, such as services, intellectual property and investments, as well as a new and definite institutional structure for the operation of the overall system and a more efficient dispute settlement machinery. These new issues, together with the need (mostly the needs of developed nations) to reframe the world system of trade regulation, led to a set of very complex diplomatic and political negotiations, making the Uruguay Round objectives, as described in the Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations[103], an amazingly difficult task.

On 15 April 1994, 124 States signed, in Marrakesh, the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (the "Final Act")[104], under the auspices of GATT. The Final Act incorporates an Agreement

---

[101] As the GATT did not come into force, because of the failure to put the Havana Charter into effect, the GATT has been applied provisionally, since 1948, under the provisions of the Protocol of Provisional Application (PPA), by Australia, Belgium, Canada, France, Luxembourg, the Netherlands, the United Kingdom and the US. Governments that acceded to the GATT after 1948 did so on the terms and provisions of their protocols of accession. See, for more detailed information, and for an analysis of the text of the PPA, **GATT**, note 99, *supra*, pp. 993-1006. It is also worth mentioning that the envisaged ITO would be part of the UN system through a specialised agency agreement with the UN Economic and Social Council, under Article 63 of the United Nations Charter. As the ITO was never established, the GATT "... is treated as a specialized agency on a *de facto* basis", though the GATT has never established any formal relationship with the United Nations (*Ibid.*, p. 1041).

[102] Seven rounds of negotiations preceded the Uruguay Round, as follows: Geneva (1947), Annecy (1949); Torquay (1950); Geneva (1956); Dillon (1961); Kennedy (1962 to 1967); and Tokyo (1973 to 1979). The first five rounds addressed essentially tariff-reduction matters. Then, the Kennedy Round was designed to look more seriously at the non-tariff barriers issues, but was concluded with little success. Lastly, the Tokyo Round was the major round of negotiations which attained further the objectives of reducing non-tariff barriers to trade (**John H. Jackson,** Reestructuring the GATT System, London: Royal Institute of International Affairs (1990), p. 36).

[103] Published in 25 ILM 1623 (1986). Hereinafter the "Ministerial Declaration".

[104] Published thoroughly in **GATT**, The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts, Geneva: GATT Secretariat (1994).

Establishing the World Trade Organization (WTO)[105], which creates the institutional framework of the successor of GATT, the WTO. It has also several agreements, in various areas, attached to it. Among others, there is the General Agreement on Trade in Services (Annex 1B), the Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C)[106], and the Understanding on Rules and Procedures Governing the Settlement of Disputes (Annex 2). A more comprehensive view of the institutional framework of the WTO is provided below in Appendix II, Chart 2.

2.1. IPRs in the GATT framework

Since its beginning, the GATT system has dealt marginally with the issues on IPRs, though it has accepted that IPRs may become barriers to international trade, and should be regulated somehow. In accordance with the GATT Secretariat[107], there are two types of provisions that are relevant in the analysis of these issues, and some further provisions in other instruments negotiated under the GATT auspices.

Firstly, the GATT lays down general rules or procedures capable of bearing upon some aspects of IPRs related to international trade, although they do not address the issues of IPRs directly. They are, *inter alia*, Article I (2) and (4), on the application of the Most-Favoured-Nation clause; Article III (4), on the application of the National Treatment principle; Article XI (1), on the general elimination of quantitative restrictions; and Article XIII, on non-discriminatory application of quantitative restrictions. As emphasised by the GATT Secretariat,

---

[105]Hereinafter the "WTO Agreement". The WTO Agreement came into force on 1 January 1995 with seventy six members (*WTO Focus*, N. 1, January/February 1995, p. 5). As at 1 July 1995, the WTO Agreement had already 100 members (*WTO Focus*, N. 3, May/June 1995, p. 5).
[106]The "TRIPS Agreement".

> The General Agreement contains basic rules and principles on governmental measures affecting the importation and exportation of goods as well as on certain internal governmental measures affecting trade. These rules and principles apply to all such measures irrespective of the policy area in which they are taken. They, thus, also apply to such measures when taken in connection with intellectual property rights.[108]

Still, according to the analysis of the GATT Secretariat, there are some provisions in agreements negotiated under the auspices of GATT which should be understood as referring to trade-related aspects of IPRs. These instruments are the Agreement on Technical Barriers to Trade; the Agreement on Implementation of Article VII of the GATT; and the Arrangement Regarding International Trade in Textiles.[109]

As this research deals essentially with international trade and patent protection, a more limited approach to the subject shall be taken. The present Sub-section will consider in more detail only the provisions suggested by the GATT Secretariat as referring specifically to IPRs. They are Articles IX, XII (3)(c)(iii), XVIII (10), and XX (d).

Article IX, entitled "Marks of Origin", refers essentially to marking requirements and the marking of imported products and trade names, making sure that they are not used in a way which could obstruct the liberalisation of international trade or that they could be used as discriminatory measures between Contracting Parties. These marking requirements are present in paragraphs 1 to 5 of Article IX,

---

[107]GATT Doc. N. MTN.GNG/NG11/W/6 (22 May 1987) GATT Provisions Bearing on Trade-Related Aspects of Intellectual Property Rights. Note by the Secretariat.
[108]*Ibid.*, p. 1.
[109]*Ibid.*, p. 6.

and paragraph 6, which is mainly concerned with the protection of geographical indications related with marking requirements.

Articles XII (3)(c)(iii) and XVIII (10), on the other hand, refers to certain conditions in which Contracting Parties are allowed to use import restrictions to safeguard their balance of payments. Both provisions, however, "... prohibit these restrictions from being applied so as to prevent compliance with patent, trademark, copyright or similar procedures"[110].

Article XX (d) is a general exception to governmental measures, such as those related to IPRs, that are allowed to secure compliance with the laws of IPRs. Article XX (d), thus, reads as follows:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction to international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> .....
>
> (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provision of this Agreement, including those relating ..., the protection of patents, trademarks and copyrights, and the prevention of deceptive practices.

A GATT Panel has discussed the subject under Article XX (d) when relating to patent infringement and noted the following:

> The Panel noted that the GATT recognized, by the very existence of Article XX (d), the need to provide that certain measures taken by a contracting party to secure compliance with its national laws or regulations which otherwise would not be in conformity with the GATT obligations of that contracting party would, through the application of this provision under the conditions stipulated therein, be

[110] *Ibid.*, p. 5, para. 15.

> in conformity with the GATT provided that national laws or regulations concerned were not inconsistent with the General Agreement. In this connection the Panel noted in particular that the protection of patents was one of the few areas of national laws and regulations expressly mentioned in Article XX (d).[111]

2.2. IPRs during the Tokyo Round

More effective concerns in relation to IPRs and international trade took place during the late 1970s, when the International Anti-counterfeiting Coalition was created, with the participation of 100 multinational corporations, "... to lobby national governments to strengthen protection against counterfeit trademarked goods"[112]. Eventually, this Coalition continued to raise efforts towards more substantive discussion on all forms of intellectual property protection, which led to the inclusion of the theme in the Uruguay Round of negotiations[113]. This Sub-section was therefore included in this Chapter as a necessary background to the negotiations which led to the TRIPS Agreement.

The US government had considered the effects of the growing market for counterfeiting trade-marked goods, and raised this point in the GATT framework for the first time in June 1978, in the Tokyo Round Sub-group on Customs Matters[114]. Draft rules on anti-counterfeiting were then prepared by the US and other delegations, and a proposal for an agreement in this area was circulated in December 1978 among

---

[111]Document L/5333, adopted on 26 May 1983, 30S, pp. 124-125, para. 53, *apud* **GATT**, note 99, *supra*, p. 538.

[112]**Julie Chasen Ross & Jessica A. Wasserman**, Trade-Related Aspects of Intellectual Property Rights, in **Terence P. Stewart** (ed.), The GATT Uruguay Round: A Negotiating History (1986-1992), Deventer/The Netherlands: Kluwer Law and Taxation Publishers (1993), p. 15, note 83.

[113]*Ibid.*

[114]GATT Doc. N. MTN.GNG/NG11/W/4 (6 May 1987) Work Undertaken in GATT Concerning Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Note by the Secretariat, p. 2, para. 3.

the Contracting Parties of the GATT[115]. From October to November 1979 other draft texts of an agreement were circulated among the Contracting Parties of GATT, but at the conclusion of the Tokyo Round an agreement was not reached[116].

The US government, with the support of Canada, the European Communities and Japan, continued efforts to include the matter in the GATT framework. As a consequence a Ministerial Declaration of the GATT Contracting Parties, of 29 November 1982, decided that the Council of Representatives of GATT should examine the "appropriateness of joint action" within the GATT, and, if such was found necessary, the Director General of the GATT Secretariat would be requested to hold consultations with the Director General of WIPO aiming at clarifying the legal and institutional aspects related with trade in counterfeit goods[117].

After consultative meetings between the GATT and the WIPO Secretariats took place, a report was issued and a Group of Experts on Trade in Counterfeit Goods was formed. This matter was gaining more importance and becoming part of a major concern in the GATT framework. More substantive actions were decided, then, in the Ministerial Declaration of Punta del Este, when the Uruguay Round was launched in 1986[118].

The latest version of the "Agreement on Measures to Discourage the Importation of Counterfeit Goods"[119] evidently shows that the desire to discourage

---

[115]*Ibid.*, para. 4.
[116]*Ibid.*, para. 5.
[117]*Ibid.*, para. 7.
[118]*Cf.* note 103, *supra*. The negotiating objectives for the discussion of Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, as described in the Ministerial Declaration of 20 September 1986 will be referred to, in more detail, in Sub-section 2.3, *infra*.
[119]Hereinafter the "Agreement on Counterfeit Goods". As reissued to participants of the Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit

international trade in counterfeit goods, through co-operation among participating countries, was designed to create measures to protect the rights of trade-mark owners[120], laying down minimum requirements to discourage international trade in counterfeit goods[121].

Parties would be required, therefore, to provide trade-mark owners with administrative and/or judicial mechanisms to initiate procedures to protect their rights, before goods were released from the jurisdiction of customs authorities[122]. The trade-mark owner initiating administrative or judicial procedures should be required to produce "... satisfactory evidence that counterfeit goods are in the process of being, or are likely to be imported"[123]. National authorities would, consequently, take the necessary steps to retain jurisdiction over the importation of counterfeit goods, once satisfied with the evidence provided by the trade-mark owner[124]. A national treatment-type of rule would also apply in so far as "[t]he criteria by which the authorities determine whether imported goods are counterfeit shall be no less favourable than the criteria used to determine whether domestically produced goods are counterfeit"[125].

Developing countries would be given an extra period of up to two years from the date of entry into force of the Agreement on Counterfeit Goods to apply its provisions. They would also be able to receive, upon request and on mutually agreed

---

Goods, of the Uruguay Round, in GATT Doc. MTN.GNG/NG11/W/9 (25 June 1987) Draft Agreement to Discourage the Importation of Counterfeit Goods.

[120] Agreement on Counterfeit Goods, Preamble and Art. 1.

[121] *Ibid.*, Art. 1.3.

[122] *Ibid.*, Art. 2.1.

[123] *Ibid.*, Art. 2.2. In accordance with a note to Article 2.2., which would be part of the Agreement on Counterfeit Goods, by virtue of Article 6, "[t]he phrase 'or likely to be imported' is intended to provide a means whereby the owners of the trademark rights may initiate procedures, where the country of importation so provides, in cases were alleged counterfeit goods have not yet come within the jurisdiction of customs".

[124] *Ibid.*, Art. 2.3.1.

[125] *Ibid.*, Art. 2.5.

terms, advice and assistance from developed countries, in relation with, *inter alia*, training of personnel, assistance in preparing implementation measures, and advice on the control and identification of imported counterfeit goods.[126]

The Agreement on Counterfeit Goods would be serviced by the GATT Secretariat[127], and a Committee on Measures to Discourage the Importation of Counterfeit Goods would be created to administer the provisions of the agreement and to afford Parties with the opportunity to consult on any matters relating to the operation of the Agreement or the furtherance of its objectives. Such a Committee would consist of representatives of each of the Parties, and would be required to meet at least once a year[128].

2.3. IPRs in the Uruguay Round: the TRIPS Agreement

Strictly speaking, the work for the setting up of an institutional and legal framework for an agreement, under the GATT auspices, concerned with trade-related aspects of intellectual property rights, started with the unsuccessful negotiations of the Agreement on Counterfeit Goods. A more practical approach associated with intellectual property issues in GATT, nevertheless, took place in Punta del Este, Uruguay, on 20 September 1986, when Ministers adopted the Ministerial Declaration on the Uruguay Round[129], establishing the objectives of the negotiations to address TRIPS matters, as follows:

---

[126] *Ibid.*, Art. 8.
[127] *Ibid.*, Art. 9.9.
[128] *Ibid.*, Art. 7. In addition to that, Article 7 affirms that dispute settlement procedures would be subject to Articles XXII and XXIII of the GATT and the Understanding on Notification, Consultation, Dispute Settlement and Surveillance.
[129] *Cf.* note 103, *supra*.

> In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines.
>
> Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT.
>
> These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organization and elsewhere to deal with these matters.

It is possible to highlight, at least, three major points of interest expressed by the Ministerial Declaration. Firstly, it is acknowledged that non-uniform protection of IPRs on a world-wide basis may become a barrier to trade, and that GATT should clarify its own provisions and elaborate common rules and principles accordingly. Secondly, the Ministerial Declaration recognised the work already carried out in the field of counterfeit goods, including this subject also in the framework of the future negotiations of TRIPS. Finally, it expressed a respect towards the work of other international organisations, in particular those of the WIPO. These are the basic rules which should have been followed by the negotiating group on TRIPS. It is argued by some developing countries, however, that TRIPS negotiating group went far beyond its mandate, discussing substantive intellectual property principles, and imposing minimum standards which do not take into consideration the technological gap between North and South[130].

---

[130]See, generally, GATT Doc. N. MTN.TNC/MIN (90)/ST/46 (4 December 1990) India - Statement by Dr. Subramanian Swany, Union Minister of Commerce, Law and Justice; GATT Doc. N. MTN.GNG/NG11/W/30 (31 October 1988) Submission from Brazil; and GATT Doc. N. MTN.GNG/NG11/W/61 (22 January 1990) Communication from Chile.

The negotiations on the TRIPS Agreement started in February 1987, when Ministers agreed on procedures for the negotiations in this field, and were carried out until 1992 when a final draft Agreement on TRIPS was issued. The TRIPS Agreement, reached at the Ministerial Meeting in Marrakesh in April 1994, contains seventy three Articles and is divided into seven parts. It contains provisions on substantive intellectual property laws, including copyright and related rights, trade-marks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, trade secrets and the control of anti-competitive practices applied to contractual licences. It also lists minimum requirements for the enforcement of IPRs, deals with rules relating to the acquisition and maintenance of IPRs, sets up a dispute settlement mechanism, and recognises the situation of developing countries, "transforming economies" and less-developed countries. The operation of the TRIPS Agreement is designed primarily "... to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade"[131].

The TRIPS Agreement will be administered by the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS"), established under the institutional framework of the WTO.[132] The Council for TRIPS will have the assignment of monitoring "... the operation of this [TRIPS] Agreement and, in particular, Members' compliance with their obligations hereunder, ..." and the task of

[131]TRIPS Agreement, Preamble.
[132]WTO Agreement, Art. IV (5).

providing assistance requested by the Members relating to trade-related aspects of intellectual property rights and dispute settlement procedures[133].

Two substantive GATT principles apply to the TRIPS Agreement. The "national treatment" principle implies that "[e]ach Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property"[134]. The main point here is that, within the GATT framework, this principle applies originally to goods, while within the TRIPS Agreement, the national treatment principle applies equally to right holders[135]. The establishment within the WTO framework of the operation of this principle will be certainly developed by the practice of the Agreement itself, made available by dispute settlement decisions, and enhanced by the application of this principle in other intellectual property conventions administered or not by the WIPO.

"Most-favoured-nation" treatment recognises that "[w]ith regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members"[136]. The major problem that emerged during the negotiations was that the application of this principle has never been included into other international intellectual property arrangements,

---

[133]TRIPS Agreement, Art. 68. This provision calls, also, for the establishment of co-operation arrangements with the WIPO. For a general view of the institutional mechanisms created by the Final Act, see Chart 2, Appendix II, *infra*.
[134]TRIPS Agreement, Art. 3 (1).
[135]See, *e.g.*, GATT Doc. of 26 January 1990, Checklist of Issues, Prepared by the Secretariat, p. 4, para. 6.
[136]TRIPS Agreement, Art. 4.

and, in addition, although part of the GATT framework, the "most-favoured-nation" clause has been applied primarily to goods, not to right holders[137].

It is also important to note that the TRIPS Agreement proposes the establishment of minimum standards which should be adopted by national law. However, there is no restriction on adopting higher standards of IPRS than those proposed by the TRIPS Agreement, in so far as such protection does not run against its provisions. Members have, in addition, the discretion to include the minimum requirements of the TRIPS Agreement in their national laws and practices by the method that they deem appropriate and necessary[138]. Furthermore, the TRIPS Agreement will have binding force once ratified by Members, but will be enforced under the new international trade system only after an additional period of time granted solely to less developed countries[139].

---

[137]Note 135, *supra*, p. 6, para. 17.

[138]TRIPS Agreement., Art. 1 (1).

[139]*Ibid.*, Art. 65. Generally, Members will be obliged to apply the provisions of the TRIPS Agreement within one year from the date of entry into force of the WTO Agreement (*Ibid.*, Art. 65 (1)). However, developing countries and "transforming economies" have been granted an extra period of four years (*Ibid.*, Arts. 65 (2) and (3), respectively). In addition, the extra period for "least-developed" countries is ten years (*Ibid.*, Art. 66). The application of this provision has caused, particularly in Brazil, a major discussion within the Brazilian Association of Intellectual Property (ABPI). Industrial property agents started to debate the subject because of the publication of Brazilian Decree N. 1.355, of 30 December 1994, in the Official Journal of Brazil on 31 December 1994, which is the legal instrument ratifying the Final Act. In Article 2, Decree N. 1.355/94 says that its provisions will enter into force on the date of publication. As a matter of interpretation, within the ABPI two school of thoughts were formed. One group believed that the fact that the Decree does not make any reservation to the entry into force of the TRIPS Agreement does not preclude the application of the extra period of time granted to Brazil, as a developing country. They argue that this is a programmatic provision that, in its essence, has included all countries within the category of developing economies. Another group argued that once a Decree is published, the international agreement becomes part of the national legal framework, without the need of further implementation, and all provisions to the contrary will be automatically revoked. This, they say, is a common understanding of national implementation of international rules. The ABPI has finally decided that the second view is one which should prevail and that the provisions of the TRIPS Agreement are already part of the Brazilian legal framework, revoking all the provisions of national intellectual property laws. This discussion, however, has not been brought before a national court yet, and the matter is, in a practical sense, still unresolved. See, for further information in this regard, **Antonella Carminati**, A Aplicação do TRIPS na Ordem Jurídica Interna, [1995] 17 *Revista da ABPI* 13-17.

The protection of "copyrights" under the TRIPS Agreement shall comply with Articles 1 to 21, and the Appendix of the Berne Convention. A substantial exception is made by the Agreement. Under the continental-European law understanding of copyrights, there are two subjects of protection. First there are "economic rights", which entitle the author to authorise reproduction, translation, or adaptation of his work, as well as its public performance; second, there are "moral rights" which entitle the author to claim authorship of his work and prevent actions prejudicial to his honour or reputation. "Moral rights" are retained by the author even after he has transferred his economic rights. Paragraph 1 of Article 9 of the TRIPS Agreement excludes the application of moral rights, when it says that Members shall not have rights under the TRIPS Agreement in respect of the rights conferred under Article 6*bis* of Berne Convention[140].

Copyright protection, under the TRIPS Agreement, shall extend to all forms of original expression, regardless of the condition in which the work is created, expressed, or embodied, or the method by which it is communicated or utilised. However, ideas, procedures, methods of operation, or mathematical concepts are excluded from protection[141]. Under the wording of the TRIPS Agreement, Members shall protect, as a minimum, all types of traditional copyrights, as well as computer programs and data compilation[142], rental rights[143], and rights of performers, producers of phonograms and broadcasting[144].

---

[140]Article 6*bis* (1) of Berne Convention reads as follows: "Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honor or reputation".

[141]TRIPS Agreement, Art. 9 (2).

[142]*Ibid.*, Art. 10.

The term of protection shall be for at least fifty years from the end of the calendar year of authorised publication, or fifty years from the end of the calendar year of the making of the work[145]. Copyright protection is based on the creation of a work, and shall subsist whether or not the work is published, communicated, or disseminated in any way. The mere fact that the work exists makes it capable of legal protection.

The TRIPS Agreement expressly accepts as the subject-matter of a "trade-mark", "[a]ny sign, or any combination of signs, capable of distinguishing goods or services of one undertaking from those of other undertakings, ..."[146].

A remarkable point, which was made in the trademark provisions of the TRIPS Agreement, is that Members are allowed to require that the signs will be visually perceptible. This reference, in the last sentence of Article 15 (1), TRIPS Agreement, seems to make reference to the fact that the smell, tastes and sounds may not be protected under trade-mark concepts[147].

The term of protection shall be for no less than seven years. The trade-mark shall be renewable indefinitely, and the renewal shall be also for a term of no less than seven years[148]. In this regard, Members are allowed to require the use of a trademark as a condition *sine qua non* for the maintenance of the registration[149], but, if they do

---

[143]*Ibid.*, Art. 11.
[144]*Ibid.*, Art. 14.
[145]*Ibid.*, Art. 12.
[146]*Ibid.*, Art. 15 (1). These combinations, as provided, include personal names, letters, numerals, figurative elements and combinations of colours.
[147]During a personal interview with one of the delegates negotiating the Uruguay Round, particularly the TRIPS Agreement, it was said that some industries, *e.g.* perfume manufacturers, lobbied to include the smell as a sign capable of trade-mark protection. The last sentence of Article 15 (1), seems to make a direct reference to this fact.
[148]TRIPS Agreement, Art. 18.
[149]*Ibid.*, Art. 15 (3). Members may not, however, require actual use as a condition for filing an application for registration.

so, they are not allowed to cancel the registration before at least three consecutive years of non-use[150]. Licensing and assignment of a trade-mark is permitted, but trade-marks are not subject to compulsory licences[151].

The inclusion of the provisions aimed at the protection of "geographical indications" was essentially a proposal of the European Communities[152], supported by several other countries[153]. In the light of the TRIPS Agreement, Members are required to protect "... indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin"[154]. Members shall, therefore, refuse or invalidate the registration of a trade-mark, *ex officio*, if the latter contains or consists of a geographical indication with respect to goods not originating in the territory indicated[155].

Special mention is made in Article 23, TRIPS Agreement, of additional protection of geographical indications for wines and spirits[156]. For the purpose of facilitating the protection of geographical indications of wine, for instance, there will be established, in the Council for TRIPS, a multilateral system of notification and registration of geographical indications for wines[157].

---

[150]*Ibid.*, Art. 19 (1).
[151]*Ibid.*, Art. 21.
[152]See, *e.g.*, GATT Doc. N. MTN.GNG/NG11/W/7 (29 May 1987) Submissions from Participants on Trade Problems Encountered in Connection with Intellectual Property Rights, p. 2, para. 3.
[153]See, generally, GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2 (2 February 1990) Synoptic Table Setting Out Existing International Standards and Proposed Standards and Principles, Prepared by the Secretariat, Revision, at pp. 68-69, for the suggestions of Australia, Switzerland, Hong Kong, Peru, Canada, New Zealand and Republic of Korea.
[154]TRIPS Agreement, Art. 22 (1).
[155]*Ibid.*, Art. 22 (3).
[156]*Ibid.*, Art. 23 (1).
[157]*Ibid.*, Art. 23 (4).

It is also noteworthy that the Council for TRIPS was given the task of keeping under review the application of the provisions on geographical indications, in which the first review will take place within two years after the entry into force of the WTO Agreement[158]. There is no such term of protection for geographical indications.

During the TRIPS negotiations, the legal protection of "industrial designs" faced a conceptual problem. International law does not provide a common definition of industrial designs and of the protectable subject-matter[159]. The Paris Convention, for instance, gives no solution to this problem. In the absence of such a conceptual approach, the principles of the EC seem to have prevailed.

Designs will, then, be protected in so far as they fulfill the requirements of novelty or originality. The design capable of protection has, thus, to differ from known designs or combinations of known designs[160]. TRIPS negotiators have decided, additionally, that industrial design rights may be kept to minimum standards, and Members may, therefore, provide that such protection will not extend to designs dictated essentially by technical or functional considerations[161]. The term of protection shall be for at least ten years[162].

In relation to "patent rights", there are several conceptual and substantive clarifications to make. The brief description of the other elements of the TRIPS Agreement, which takes place at the present Sub-section, is obviously too limited. Because the main concern of this research is the protection of patents, the issues on substantive patent law will be further considered, below, in Chapter 5.

---

[158] *Ibid.*, Art. 24 (2).
[159] See, *e.g.*, Checklist of Issues, note 135, *supra*, pp. 18-19, para. 67.
[160] *Ibid.*, Art. 25 (1).
[161] *Ibid.*, Art. 25 (1), Last sentence.
[162] *Ibid.*, Art. 26 (3).

The protection of "layout-designs of integrated circuits" shall comply, generally, with the provisions of the Treaty on Intellectual Property in Respect of Integrated Circuits[163]. Under the wording of the TRIPS Agreement, innocent purchasers of infringing products are not considered infringers, though they will have to pay the respective royalties after the notice of infringement[164]. Compulsory licences apply for layout-designs, as for patents[165].

In general terms, the term of protection is not more than fifteen years after the creation of the layout-design[166]. In countries where registration is required as a condition for the protection, the term shall be at least ten years, counted from the date of filing the application for registration, or from the first commercial use of the layout-design[167]. Moreover, in countries where registration is not required, the term of protection shall be for at least ten years from the first commercial use of the layout-design[168].

In addition to the provisions on traditional IPRs, the TRIPS Agreement governs the protection of "undisclosed information or trade secrets". Despite juridical and doctrinal doubts whether trade secrets are intangible property or "subjective rights" and, therefore, whether they are protectable under the current system of intellectual property laws[169], Article 39 (2), TRIPS Agreement, rules that Members of the WTO Agreement shall give the possibility to anyone (either natural or legal

---

[163]*Ibid.*, Art. 35. Signed on 26 May 1989. Published in 28 *ILM* 1477 (1989).
[164]*Ibid.*, Art. 37 (1).
[165]*Ibid.*, Art. 37 (2).
[166]*Ibid.*, Art. 38 (3).
[167]*Ibid.*, Art. 38 (1).
[168]*Ibid.*, Art. 38 (2).
[169]See, *e.g.*, **Stanislaw J. Soltysinski**, Are Trade Secrets Property?, [1986] 17 *IIC* 331-356, and **Sheldon Burshtein**, Confidential Information is not Property in Canada, [1988] 11 *Industrial Property* 55-58.

persons) "... of preventing information lawfully within their control from being disclosed to, acquired by, or used by other without their [owners] consent in a manner contrary to honest commercial practices ..."[170]. The conditions to be fulfilled, that protection may be granted, are the following: (a) the existence of an information which is secret; (b) the information has commercial value because it is secret and; (c) all reasonable steps have been taken to keep the information secret. In the absence of any provision regulating the term of protection of undisclosed information, it is possible to affirm that the TRIPS Agreement grants protection for valuable undisclosed information for an unlimited duration, if the conditions above listed are met.

The provisions on the protection of undisclosed information deal also with another form of trade secret protection. When Members require, as a condition for the approving of the marketing of pharmaceutical or agricultural chemical products, the submission of undisclosed information, test or other data, such information shall be protected against unfair commercial use and against disclosure, except where necessary to protect the public[171].

In relation to protection against "unfair competition", there was general agreement among industrialised nations that some degree of control over licensing, where the licensing agreement has anti-competitive effects - thus having adverse effect on trade and impeding the transfer and dissemination of technology[172] - should exist in

---

[170]The TRIPS Agreement defines, in a footnote to Article 39 (2), that "'a manner contrary to honest commercial practices' shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition".

[171]TRIPS Agreement, Art. 39 (3).

[172]*Ibid.*, Art. 40 (1).

the TRIPS Agreement. Members are, therefore, allowed (but there is no obligation to do so) to "... adopt, ..., appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing"[173]. Further discussion of the TRIPS Agreement's approach towards competition law principles takes place in Chapter 6, Section 2, Sub-section 2.1, Paragraph 2.1.2, *infra*.

The need of stronger rules, in a multilateral level, for the "enforcement of IPRs" was one of the major arguments for the inclusion of the issues on IPRs in the context of the Uruguay Round. The US, for instance, has claimed that the international agreements administered by the WIPO did not provide for appropriate rules for the enforcement of IPRs[174].

Accordingly, the TRIPS Agreement requests that Members should establish national rules to ensure the enforcement of IPRs, in a fair and equitable way[175], "... so as to permit effective action against any act of infringement of intellectual property rights covered by this [TRIPS] Agreement"[176]. Therefore, decisions on the merits of a case should be preferably in writing and reasoned, and made available to the parties of the proceeding without undue delay[177]. Parties should also be given the opportunity of judicial review of final administrative decisions[178]. In fact, the TRIPS Agreement goes beyond these basic rules, providing that Members shall provide intellectual property owners with several legal mechanisms, such as due process, evidence, fair

---

[173] *Ibid.*, Art. 40 (2).
[174] See, *e.g.*, GATT Doc. N. MTN.GNG/NG11/W/2 (3 April 1987) Statement by the United States at Meeting of 25 March 1987.
[175] TRIPS Agreement, Art. 41 (2).
[176] *Ibid.*, Art. 41 (1).
[177] *Ibid.*, Art. 41 (3).
[178] *Ibid.*, Art. 41 (4).

hearing and motivation of decisions, appeals, delays, provisional measures and preliminary injunctions, *ex officio* actions by border authorities, and damages and criminal sanctions related to trademark and copyright infringements.[179]

As it is generally known, the WTO Agreement improved the dispute settlement mechanisms for the resolution of disputes among countries. This has been one of the major achievements of the Uruguay Round which improved the procedural rules of the system providing for a binding-type of rulings regarding the resolution of conflicts[180]. The system of the WTO will apply equally to disputes within the framework of the TRIPS Agreement[181].

CONCLUSION

This Chapter has attempted to provide a general background on the establishment of multilateral agreements in the field of patent protection. As has been seen, the development of an international patent system is part of a historical process which considered the various stages of technology and human knowledge.

This complex set of rules must be taken into account within the context of the negotiations of the MERCOSUL. The international commitments of each State Party of the MERCOSUL has to be part of the negotiating process. Of course diplomatic and technical negotiations are considering a common regime for patent protection for the MERCOSUL which is compatible with the international commitments of the States Parties. But, as has been briefly described above, this group of rules and

---

[179]See, generally, TRIPS Agreement, Part III.

[180]For further analysis of the issues on dispute settlement as an outcome of the Uruguay Round, see *e.g.*, **Lei Wang**, Some Observations on the Dispute Settlement System in the World Trade

international norms are complex and sometimes confusing. Within this complexity, the MERCOSUL has to find out how to address issues on transfer of technology, proprietorship of technology and knowledge, in ways which recognise the technological needs of the region.

There are two institutional approaches, at international level, that are of relevance in this context. The MERCOSUL, firstly, has to act jointly in the international debate as a means of defending its own interests as a common integrated area and also as individual countries. States Parties must consider the development of the negotiations both within WIPO and within WTO, to take account of certain circumstances that are particularly connected with the unfair technological gap between developed and developing world.

The MERCOSUL, as such, has a political strength in the international debate which is to be considered as a means of attaining the goals of multilateralism in the international patent discussion. If one takes the example of the negotiations during the Uruguay Round, it is clear that although developing countries sometimes acted together, they were unable to include most of their propositions into the TRIPS Agreement. The outcome of the latter was clearly a position in favour of the developed world as proprietors of technology. But, at the end of the day, developing countries were granted at least an extra period of time to implement these provisions, which is a recognition of their lack of technological competitiveness.

The second approach, that should be taken by the MERCOSUL, derives from the recognition that international negotiations in the field of patent protection are

---

Organization, [1995] 29 *JWT* 173-178, and **Gary Horlick**, Dispute Resolution Mechanisms - Will the United States Play by the Rules?, [1995] 29 *JWT* 163-172.

moving towards a stricter and more detailed legal framework which embraces several aspects of the protection of technology. If regional arrangements in developing countries, such as the MERCOSUL, do not include patent protection as part of their common science and technology strategy, they will have to face a situation in which they become even weaker players, merely buying technology. They have to include, in their common legal framework for patent protection, mechanisms which grant them some degree of flexibility against the commercial and technological power of the industries of the developed world, such as regulations on prices, anti-competitive practices and abuse of dominant position. A country and, in this case, an integrated area have to control the participation in the market of both their own industries and undertakings as well as their foreign counterparts.

A common mechanism for the protection of patents in the MERCOSUL must indeed consider transfer of technology as part of a policy which aims at technological development in the region. This is to be achieved by common actions in this field and co-ordinated establishment of national policies in science and technology. If States Parties of the MERCOSUL are primarily buyers of modern technology, they must invest highly in developing their own technology, at least based on the existing technology that they are buying. It does not seem that the international debate in this field will consider further the weak position of developing countries. It is neither clear whether international negotiations will consider further mechanisms for technology transfer under most favoured treatment to the developing world. It appears that the international discussion will rather approach the subject in a way to provide

---

[181] TRIPS Agreement, Art. 64.

multinational undertakings with stronger position in the international and highly competitive market of technology.

A common legal framework for the protection of patents in the MERCOSUL will have to examine, additionally, the commercial issues related to the implementation and functioning of an integrated area. This will be further studied below in Chapter 3, as a means of providing an example of an integrating process such as the European one. Additionally, some deeper discussion is necessary in the field of unification of institutional mechanisms and substantive patent laws within an integrated arrangement. This will be examined in more detail in Chapter 4, also taking into consideration the European experience.

CHAPTER 3
PATENT LAW AND THE EC TREATY

INTRODUCTION

The MERCOSUL, as has been seen above in Chapter 1, Section 2, is an infant integrating experience. The example of the European Community (EC) may be of relevance to the MERCOSUL in several respects, particularly when one considers the protection of patents, the exercise of the rights conferred upon a patent and the effects that this exercise may have in an integrated area. The legislative and juridical experiences of the EC have been developed for more than three decades and undoubtedly throws light on prospects for the MERCOSUL. It is necessary to mention, however, that both integrating projects have distinct goals and characteristics and the experience of the EC cannot be just copied to the MERCOSUL. The analysis that follows is an attempt to provide the Southern Cone project with some of the legal and juridical problems that may arise in different forms in the MERCOSUL.

This Chapter considers the effects of EC law on patent rights. The protection of these rights by national law will be dealt in the light of the Community context to the extent which EC law affects the traditional exercise of national patent rights. It is thus necessary to analyse the basic rules protecting the free movement of goods[1] and the legal framework aiming to establish a system of competition within the Common Market which is not distorted[2]. Although it seems that both group of rules are

---

[1] EC Treaty, Arts. 30 to 36.

[2] *Ibid.*, Arts. 85 and 86. As secondary sources, this Chapter utilises Regulation N. 17/62 (OJ, Special Edition, 21/2/62, 87), implementing the above mentioned provisions (hereinafter the "Regulation 17") and Regulation 240/96 of 31 January 1996 (OJ 1996 L31/2), on the application of Article 85 (3) of the Treaty to certain categories of technology transfer agreements (hereinafter the "Regulation

distinct, since each operates in its own particular way, and both are part of the objectives of the Treaty Establishing the European Community[3] listed in Article 3, conflicts emerge from the application of these rules. It is important to understand the relationship between the rules relating to the free movement of goods and the rules relating to competition within the Community in order to clear up the discussion that follows in this Chapter.

While Articles 30 to 36 are addressed to the Member States, and all its governmental bodies in all levels, to ensure no restriction on the free flow of products within the territory of the Common Market, Articles 85 and 86 are directly addressed to undertakings and, to operate, it requires an agreement, decision by undertakings or concerted practices between at least two undertakings, or the existence of a dominant position "... within the Common Market or in substantial part of it"[4], which affects, or may affect, trade between Member States of the EC. If two undertakings breach the rules of competition, they may incur fines and penalties from the European

---

240/96). The present analysis provides also an outline of Regulation N. 2349/84 (OJ 1984 L219/15, *corrigendum* OJ 1985 L113/34), on block exemptions for patent licensing agreements (hereinafter the "Regulation 2349/84"), and of Regulation N. 556/89 (OJ 1989 L61/1), on block exemptions for know-how licensing agreements (hereinafter the "Regulation 556/89"). The last two Regulations as amended by Regulation N. 151/93 (OJ 1993 L21/8).

[3]Published in **Nigel Foster** (ed.), Blackstone's EC Legislation, London: Blackstone Press Limited (1995), 6th ed.. As amended by the Treaty Amending Certain Financial Provisions, the Single European Act, the Merger Treaty, the Greenland Treaty, the Acts of Accession and the Treaty on European Union (Maastricht Treaty). Hereinafter referred to as either the "Treaty" or the "EC Treaty". As a matter of clarification, it is important to note that "[t]he Treaty on European Union created the 'European Union', which consists essentially of the three so-called pillars: the central pillar is the existing communities [the European Coal and Steel Community, the European Atomic Energy Community, and the former European Economic Community which is now called, as amended by the Maastricht Treaty, the European Community] and their law (...). The two other pillars comprise provisions on common foreign and security policy and provisions on co-operation in the fields of justice and home affairs" (**David A.O. Edward & Robert C. Lane**, European Community Law: An Introduction, Edinburgh: Butterworths & Law Society of Scotland (1995), 2nd ed., p. 12, para. 37).

[4]EC Treaty, Art. 86.

Commission (the "Commission"). On the other hand, in the case of breaching Articles 30 no such sanction is available to a government.

Below, it will be seen that several cases involving the disputes of intellectual property rights, however, are dealt with under the free movement of goods and competition provisions.[5] Goyder, analysing the relationship between both groups of provisions of the Treaty, states that:

> The European Court of Justice might well seek, as a matter of policy, to limit the application of Article 30 to situations other than those when the Commission itself had, after protracted consultation and negotiations, established a model for patent licensing arrangements within the Community which it followed would not in its view restrain competition within the terms of Article 85.[6]

Afterwards, the author sums up the question concluding that "[t]he Court would be likely to seek a solution which harmonized the approach of the two Articles [Articles 30 and 85 of the Treaty] rather than emphasized the differences between them"[7].

As will be seen in detail below, principles such as the doctrine establishing the distinction between the existence and the exercise of intellectual property rights have been developed in the context of one of the provisions of the Treaty (either Articles 30 to 36 or 85 and 86), but apply to the others. The link between both groups of provisions is quite clear as far as an agreement between undertakings or an abuse of a

---

[5] See, as an example, cases listed in notes 12 and 13, *infra*.
[6] **D.G. Goyder**, EC Competition Law, Oxford: Oxford University Press (1993) 2nd ed., pp. 337-338.
[7] *Ibid.*, p. 338.

dominant position, which affect trade between Member States, may, as a consequence, restrict the free flow of goods within the Community.[8]

Note, finally, that the following methodology was used in Sub-section 2.1. (Analysis of Article 85). This Sub-section firstly provides a general overview of the application of Article 85, EC Treaty. Then, the most important - and/or the most complex - clauses in patent licensing agreements are described in some detail. Following that, Paragraph 2.1.2. provides a general view of the legal mechanisms available in the EU to regulate patent and know-how licensing agreements.

It may seem, for the reader, that there is an overlap between Paragraph 2.1.1. and Paragraph 2.1.2., below. While the former suggests to include in the discussion some of the the clauses commonly present in patent or know-how licensing agreements, the latter describes, Article by Article, the contents of Regulation 240/96.

This Regulation focuses, indeed, on block exemptions for patent and know licensing agreements, and determines which clauses are - and are not - to be deemed as within the wording of Article 85 (3), EC Treaty. Regulation 240/96 focuses also on other procedural matters for the appropriate application of Article 85 (3), which should be generally described.

Paragraph 2.1.2. provides, only, a general overview of past Regulations on block exemptions for patent (Regulation 2349/84) and know-how (Regulation 556/89) licensing agreements, briefly listing the provisions of Regulation 240/96. Paragraph 2.1.1., on the other hand, discusses in more detail particular clauses which should be analysed with further care by the integrating process of the MERCOSUL.

---

[8]See, *e.g.*, Case T-51/89 ***Tetra Pak* v. *Commission*** [1990] ECR II-309, [1991] 4 CMLR 334, and **Derrick Wyatt & Allan Dashwood,** European Community Law, London: Sweet & Maxwell Ltd.

1. THE FREE MOVEMENT OF GOODS

The provisions of the Treaty related to the free movement of goods are Articles 3 (a)[9], 9 and, as "substantive provisions", Articles 30 to 37. The present discussion will be based on the aspects of Article 30, which states the prohibitions, and Article 36 which states the exceptions of the prohibitions established by Article 30. The main purpose of the Treaty is to create an integrated economic system similar to national systems. Hereupon, an exclusive monopoly granted by the State within its territorial jurisdiction to an individual, as the case of a patent, appears to be incompatible with the provisions of the Treaty creating an area where goods shall circulate freely.

The European Court of Justice (the "Court"), analysing the characteristics of patent protection, declared that the holder of a patent has the right to exploit the invention for the purpose of making and selling the patented product and hence the right to prevent an infringement by a third party that is manufacturing and/or selling the patented product without the owner's consent. The connection between the exercise of these rights and the application of the common principles of Community law had to be developed further to reach a balance between national and Community interests.

(1987) 2nd ed., pp. 613-615, for the relationship between Articles 85 and 86 and the relationship between both Articles and Article 30 of the EC Treaty.

[9]Article 3 (a) states that, for the purposes of establishing a Common Market, the activities of the Community shall include "the elimination, as between Member States, of customs duties and quantitative restrictions on the import and export of goods, and of all measures having equivalent effect". As emphasised by **Diana Guy & Guy Leigh**, The EEC and Intellectual Property, London: Sweet & Maxwell Ltd. (1981), p. 5, "... the link between this and intellectual property is to be found in the innocuous phrase 'all measures having equivalent effect'". For further discussion in this regard see, also, **R. Barents**, New Developments in Measures Having Equivalent Effect, [1981] 18 *CML Rev.* 271-308.

1.1. The distinction between the existence and the exercise of a patent right

National rules governing intellectual property rights within the Community are, on the one hand, protected by Article 222[10] and by Article 36 of the Treaty. On the other, Article 30, aiming to ensure the free circulation of goods throughout the Community, determines that "[q]uantitative restriction on imports and 'all measures having equivalent effect' shall, ..., be prohibited between Member States"[11]. It is clear that there is conflict between the existence of IPRs, protected by the Treaty and granted by national legislation, and the effects of the exercise of these rights on the rules ensuring the circulation, without restrictions, of goods within the territory of the Community. In several judgments the court has held that the exercise of a national intellectual property right in a way that prevents the free circulation of goods constitutes a "measure having equivalent effect" to a quantitative restriction and, under Article 30 of the Treaty, it is prohibited.

The European Court of Justice developed the distinction between the existence of IPRs and its exercise, seeking to set out a balance between the requirements of Community and national laws. It seems that the Court gave priority to the needs of the Community when it stressed that the existence of national rights is not affected either by Articles 30 to 34 or by Articles 85 and 86, but its exercise in some ways may contravene the rules of the Treaty.

---

[10]Article 222 establishes the following: "The Treaty shall in no way prejudice the rules in Member States governing the system of property ownership".
[11]*Cf.* note 9, *supra*. Emphasis added.

Although the distinction was first developed in cases under the application of Article 85 (1)[12], and related to trade-marks, later the principle was reaffirmed in cases dealing with Articles 30 to 36[13]. Henceforth, despite some criticisms, the distinction became clearer in the sense that "... it is only the 'existence' of the right which is safeguarded by Article 36 [and Article 222] and that the 'exercise' of the right is subject to limitations arising from the rules of the Treaty"[14]. Indeed, the limitations arise from the rules provided by the Treaty but are enforced by the Commission and by national courts, and imposed by the interpretation of these rules by the European Court of Justice.

The development of the distinction, on the points which have been discussed above, leaves patent rights granted by national legislation intact, because the existence of these rights cannot be incompatible with Articles 30 to 34. The conflict emerges solely when these rights are exercised. Hereupon the Court limits its practice.

The Treaty left discretion to protect IPRs with the Member States, but controls its exercise to the extent to the limits of the common rules of the Community. "In practical terms, this implies,..., that each Member State is free to define what constitutes the novelty for a patent, but once it has granted the right it cannot allow its

---

[12]See Joined Cases 56 & 58/64 ***Consten & Grundig* v. *Commission*** [1966] ECR 299, [1966] CMLR 418, when the Court firstly developed the distinction. See, also, Case 40/70 ***Sirena* v. *Eda*** [1971] ECR 69, [1971] CMLR 260.

[13]See Case 78/70 ***Deutsche Grammophon* v. *Metro*** [1971] ECR 487, [1971] CMLR 631. In relation with patents, however, the Court firstly affirmed the distinction in Case 24/67 ***Parke, Davis & Co.* v. *Centrafarm*** [1968] ECR 55, [1968] CMLR 47 and, later, analysing disputes under the provisions regulating the free movement of goods, the Court reaffirmed the distinction in Joined Cases 15 & 16/74 ***Centrafarm* v. *Sterling Drug*** [1974] ECR-II 1147, [1974] 2 CMLR 480.

[14]**Vivien Rose** (ed.), Bellamy & Child Common Market Law of Competition, London: Sweet & Maxwell Ltd. (1993) 4th ed., p. 491.

holder to act in ways incompatible with the objectives of the Treaty concerning the free movement of goods and competition"[15].

By conclusion, one can see that the balance reached by such a doctrine is of great importance to set up the private interests of the patentee and the public interest of free trade within the Community. The patent holder draws advantage from the monopoly granted to him, but this monopoly cannot be exercised freely, it has to be limited to fit in with the Community interest.

A not unimportant procedural point to refer is that the conflict between the existence and the exercise of IPRs has been seen quite commonly, and has been resolved by different levels of discussion: administrative and judicial. As an example, when a company lodges a complaint with the Commission that firms from another Member State are unfairly invoking their national patent law to prevent the importation of goods from a different Member State, the conflict may be solved by administrative methods with the intervention of the Commission. Nevertheless, it is more common that these conflicts are discussed on the level of the national courts as well as on the level of the European Court of Justice. This point will be discussed in more details in the next Section which analyses the rules of the Treaty which regulate competition law.

A final point, which must be mentioned, is that the development of this doctrine is considered by many as a paradox of the essence of an intellectual property right. The existence of IPRs is intrinsically related with their exercise. If no rights to exercise a patent exist, no reason would be found to have a patent right. This,

---

[15]**G. Friden**, Recent Developments in EEC Intellectual Property Law: the Distinction Between Existence and Exercise Revisited, [1989] 26 *CML Rev.* 193-218, p. 194.

although confusing for many, is an approach that may be the outcome of further developments of the doctrine of "existence against exercise"[16]. It is important to say, however, that the Court has probably developed such a doctrine as a compromise given the existence of non-uniform systems of laws for the protection of intellectual property within the EC. If one considers, as in the case of patents, that a "Convention for the European Patent for the Common Market"[17] has not come into force yet, maybe this was not the best way for the Court to reach a balance between different systems of laws and the EC system, but since the establishment of the doctrine of "existence against exercise" it has proved that it was not entirely useless or lacking practicability.

1.2. The exhaustion of patent rights and the doctrine of the specific subject-matter

The distinction between the existence of national patent rights and their exercise was defined above in the light of the provisions of the Treaty and through its interpretation by the Court. Once the holder of a patent manufactures and markets his product, he is exercising the right granted by the State upon his invention. Then, limitations on this exercise arise.

---

[16]From more recent decisions of the Court, it appears that such a doctrine is become of marginal importance within the context of the application of IPRs in the Common Market. See, *e.g.* **Guy Tritton**, Articles 30 to 36 and Intellectual Property: Is the Jurisprudence of the ECJ Now of an Ideal Standard?, [1994] 10 *EIPR* 422-428, p. 423, and **Clifford G. Miller**, Magill: Time to Abandon the 'Specific Subject Matter' Concept, [1994] 10 *EIPR* 415-421, p. 419.

[17]Known as the Community Patent Convention (CPC). See Chapter 4, *infra*, for further discussion on the aspects of the implementation of a common patent system for the common market through the establishment of a multilateral agreement between Member States of the EC.

The doctrine of exhaustion of intellectual property rights establishes that the patentee has the monopoly of the invention.[18] The patent holder, in this case, has the sole right to produce and market his invention. Nevertheless, once the patented product is lawfully marketed within the territory of the Community it must be able to circulate freely thereafter. Indeed, what the Court understands is that when the patent holder, for the first time, markets the patented product in the Community his rights are "exhausted", in the sense that "[w]hen the patentee sells a patented article he is presumed to transfer the right of free disposition of that article"[19] and, as a consequence, he cannot block the importation of this product within the Community, although, during a limited period of time, only he, or someone with his consent, has the right to manufacture the patented product. In ***Centrafarm* v. *Sterling Drug***, Advocate-General Trabucchi stated that:

> ... the patentee still retains the exclusive right to manufacture the product concerned in the country which granted the patent and to be the first to market this product. It is true that the meaning of property rights is defined by national law which creates and enforces them. But the law in force in the individual Member State cannot ignore the existence of the Community system and all this means.[20]

The development of this doctrine in the Community context is essential to guarantee the evolution of the creation of the Common Market, as the free movement of goods is one of the most important objectives to be achieved during this process. Otherwise, if the holder of a patent is able to prevent the circulation of his product within the Community he would jeopardise the application of the principles and the

---

[18]An obvious conflict emerges, as discussed in the beginning of this Chapter, when one system confers legal monopolies while another system intends to ensure free circulation of goods.
[19]**David Gladwell**, The Exhaustion of Intellectual Property Rights, [1986] 12 *EIPR* 366-370, p. 366.
[20]Case 16/74 [1974] ECR-II, note 13, *supra*, p. 1176.

achievement of the objectives established by the Treaty. The market in the Community has to be unitary, representing one single system.

The concept of the doctrine of exhaustion of rights however has to be analysed together with the development of the Court's concept on "specific subject-matter" of an intellectual property right. In ***Deutsche Grammophon* v. *Metro*** the Court held that, although the Treaty establishes prohibitions and restrictions on the matter of free movement of goods, "Article 36 only admits derogation from the freedom to the extent to which they are justified for the purpose of safeguarding rights which constitute the specific subject-matter of such property"[21]. In this case the Court first developed such a doctrine. Although the case was concerned with "sound recording" copyrights, the principle applies equally to patent, copyright and trade-mark rights.

Later, in the above-mentioned case ***Centrafarm* v. *Sterling Drug***[22], under the view that patent rights are exhausted in Community law when the specific purpose of the right has been secured by a patent holder, the Court defined, for the first time, the "specific subject-matter" of a patent right:

> In relation to patents, the specific subject-matter of the industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and "putting them into circulation for the first time", either directly or by the grant of licences to third parties, as well as the right to oppose infringements.[23]

---

[21]Case 78/70 [1971] ECR, note 13, *supra*, p. 500, para. 11.
[22]Case 16/74, note 13, *supra*.
[23]*Ibid.*, p. 1162, para. 9. Emphasis added. However, a more specific definition of the specific subject-matter of a patent right is not clear yet. See, for general criticisms on this subject, **P.A. Stone**, Some Thoughts on the Windsurfing Judgment, [1986] 8 *EIPR* 242-248.

In the same case the Court stressed the risk for the Common Market if limitations would not be imposed, when held that "if a patentee could prevent the import of protected products marketed by him or with his consent in another Member State, he would be able to 'partition off' national markets and thereby restrict trade between Member States"[24].

The link between both concepts is of great importance. Basically, the patent holder has the exclusive right to manufacture, and has the exclusive right to market the patented product for the first time[25]. However, after marketing the product for the first time, by himself or by someone with his consent, "the previous marketing 'exhausts' the ability of the owner of the right to prevent the subsequent free circulation of the products concerned throughout the Community"[26].

The patent holder enjoys the primary benefit of the right upon the patent, which means that only he, or a third party with his consent, will be able to manufacture and/or put the product on the market for the first time. If someone else, without the patentee's consent, does it, he will be infringing the patent holder's right and, consequently, the patentee will be able to oppose infringements. In that case the right is not exhausted because the specific subject-matter of that specific right has not been secured.

The Commission expressed its opinion in a White Paper entitled "Completing the Internal Market"[27], affirming that, following the rulings of the Court, "... the principle that goods lawfully manufactured and marketed in one Member State must

---

[24]*Ibid.*, Case 16/74 [1974] ECR-II, note 13, *supra*, p. 1163, para. 12. Emphasis added.
[25]The definition of the "specific subject-matter" of patent rights.
[26]**Vivien Rose**, note 14, *supra*, p. 492. The definition of the principle of "exhaustion of rights".
[27]**Commission of the European Communities**, Completing the Internal Market - White Paper from the Commission to the European Council (Milan, 28-29 June 1985), COM (85) 310 final.

be allowed free entry into other Member State", and that it would use all the powers conferred on it by the Treaty to ensure the principle for the completion of the Common Market in 1992[28].

A remarkable point relating to the application of the principle of exhaustion of IPRs is when a product originates in a third country which is not a Member State of the EC. In cases brought before English and German courts[29], related to "sound recordings" copyrights and trade-marks, respectively, it was held that the principle applies only to the free movement of goods between Member States, excluding third countries even if there is an agreement between the Community and the third country. As a general understanding, both decisions may also apply to patent rights.

The analysis of both doctrines discussed above, although not sufficient, is important to clarify the interpretation of the provisions of the Treaty ensuring the free circulation of goods within the Community and to understand the development of the principles of the Treaty by the European Court of Justice. Nevertheless, two other questions were faced by the Court: (a) when a product is not patentable in one Member State of the Community, but marketed in this Member State and imported to another Member State where it is under patent protection, if the principle of exhaustion of rights applies; and (b) the question of application of the principle in the case of the grant of a compulsory licence. These two aspects will be analysed below.

---

[28] *Ibid.*, p. 22.

[29] ***The Who Group*** **v.** ***Stage One Records*** [1980] 2 CMLR 249 (CD) and ***Deutsche Grammophon*** **v.** ***Firma Pop*** [1982] 1 CMLR 137 (BGH).

1.2.1. Product not patentable in a Member State and the application of the 'exhaustion' principle

As has been seen above, the Court drew a distinction between the existence and the exercise of intellectual property rights and held that when these rights are exercised within the Community, for the first time, by the owner of the right, directly or indirectly, they are exhausted and the product is allowed to circulate freely in the territory of the Common Market.

The Court, however, faced a question on the application of the doctrine of exhaustion of intellectual property rights in the context of a Member State which does not provide patent protection for a specific product. The point is essentially whether or not the holder of such right can prevent the importation of the patented product to another Member State where the product is patented and has been put into the market by the patent holder, or with his consent.

In a case referring to a pharmaceutical product, patented and marketed in the Netherlands by Merck & Co., and later marketed by a subsidiary of it in Italy, where such protection was not available, and, afterwards, imported back to the Netherlands by Stephar, the Court examined the question whether the rights on that product were exhausted or not, considering that the product was lawfully marketed in Italy.[30]

A prior analysis of the provisions of the Treaty leads to the concept that the national right granted by a Member State is exhausted when the product has been lawfully marketed for the first time by the proprietor of the right, or with his consent, on the market of another Member State. In ***Merck & Co.* v. *Stephar and Exler*** the

---

[30]Case 187/80 ***Merck & Co.* v. *Stephar and Exler*** [1981] ECR 2063, [1981] 3 CMLR 463.

product was marketed in Italy by a subsidiary of the proprietor of the patent with his consent.

Merck argued that the principle of exhaustion of rights is based on the premise that the proprietor of the patent should enjoy the monopoly granted by national law. This right, then, is designed to provide the inventor with the exclusive right to market the product in question for the first time and, consequently, to be recompensed for the creative effort and costs involved in the research. Otherwise, if a competitor, without any further costs, is allowed to produce and market the same product - obviously with a lower price - there would be no guarantee of recompense for creative effort and therefore no existed right protected[31].

On the other hand, according to Advocate-General Reischl's opinion, there would be no reason to talk about the exhaustion of a right within the Community "... if Merck was relying on its Netherlands patent in order to try to prohibit the reimportation of a product which its subsidiary had manufactured and exported to Italy"[32].

The Court, in its judgement, emphasised that "... it must be stated in accordance with the definition of the specific purpose of the patent,..., the substance of a patent right lies essentially in according the inventor an exclusive right of first placing the product on the market"[33]. The proprietor of the patent is free to decide under what conditions he will market the product, taking also into consideration the possibility of marketing his product in a Member State which does not provide patent protection for such product. If he decides to do so, "... he must accept the

---

[31] *Ibid.*, [1981] ECR, pp. 2070-2071.
[32] *Ibid.*, at p. 2095.

consequences [and risks] of his choice as regards the free movement of the product within the Common Market ..."[34] as a fundamental principle involving the economic circumstances that he is considering.

In conclusion, replying to the question raised by the Dutch court, the European Court of Justice held that:

> ... the rules contained in the EEC Treaty concerning the free movement of goods, ..., must be interpreted as preventing the proprietor of a patent for a medical preparation who sells the preparation in one Member State where patent protection exists, and then market it himself in another Member State where there is no such protection, from availing himself the right conferred by the legislation of the first Member State to prevent the marketing in that State of the said preparation imported from the other Member State.[35]

To sum up, in accordance with the above-mentioned judgment, the doctrine of the exhaustion of intellectual property rights was held to apply even if the product concerned was imported from a Member State which does not offer patent protection for such product, provided that the proprietor himself, or someone on his behalf, marketed the product. Otherwise, the Court emphasised, the patent holder would be able to partition off national markets, acting against the objectives and principles of the Treaty.[36]

---

[33] *Ibid.*, at p. 2081, para. 9.
[34] *Ibid.*, at p. 2082, para. 11.
[35] *Ibid.*, para. 14.
[36] *Ibid.*, para. 13. See, additionally, ruling of the Court relating to the same discussion in Case 119/75 ***Terrapin* v. *Terranova*** [1976] ECR 1039, [1976] 2 CMLR 482 (trade-mark and commercial name). It is, also, worth noting that in case ***Merck & Co. Inc and others* v. *Primecrown Ltd and others*** [1995] *Fleet Street Reports* 909, a British patent court has raised questions related with the application of such a principle developed by the Court in ***Merck & Co.* v. *Stephar and Exler***. Justice Jacob raises a question, pursuant to Article 177 of the EC Treaty, asking whether the Court should change the rule established by the Court in ***Merck & Co.* v. *Stephar and Exler*** by "... reverting the notion of exhaustion of rights at least in the case where patent protection is not available" (*Ibid.*, 909-910). Justice Jacob seems to be in favour of an over-ruling of the application of this principle and the Court might consider further developments of this doctrine.

1.2.2. Consent and compulsory licence

The question presented here is whether the owner of a parallel patent has the right to prevent the importation into the Member States where he has the patent of a product manufactured under a compulsory licence issued in respect to his patent in another Member State.

The question was brought to the Court for the first time in ***Pharmon* v. *Hoechst***[37]. In this case a compulsory licence of a drug known as "frusemide" had been granted to the manufacturer in the UK, DDSA. Pharmon purchased a consignment from the licensee to sell on the Dutch market. The holder of the patent in the Netherlands, Germany and United Kingdom, Hoechst, brought proceedings against the importation of the drug by Pharmon to the Dutch market and obtained an injunction against Pharmon, confirming that Hoechst had an exclusive licence to exploit the product in the Netherlands. Afterwards Pharmon brought an action before the Dutch "District Court" and a subsequent appeal to the "Regional Court of Appeal". The latter then requested the European Court of Justice, pursuant to Article 177 of the Treaty, to make a preliminary ruling on questions based on the application of the principles established by the Court concerning the free movement of goods within the Community.

The questions raised were essentially related to the application of the principle of exhaustion of intellectual property rights upon the grant of a compulsory licence. Pharmon, referring to the Court's decision in ***Merck & Co.* v. *Stephar and Exler***[38],

---

[37] Case 19/84 [1985] ECR 2281, [1985] 3 CMLR 775.
[38] Note 30, *supra*.

argued that the patent holder is free to decide whether to market his product and has to accept the consequences which come from his decision. Thereupon, he must consider the possibility that the national law provides for the grant of a compulsory licence to third parties. Advocate-General Mancini, however, did not accept the view of the plaintiff and concluded that there was no consent in the grant of a compulsory licence, but rather there was a decision, based on the national interest and taken by the State, imposed on the holder of the patent[39]. Understanding that there was a lack of consent by the patent holder, and emphasising the dangers of such an argument to the integration process of the EC, Mancini concluded that "...is so provided that the holder of the patent has not expressly or implicitly manifested, ..., his consent to the exploitation by third parties of the right which he holds"[40]. Therefore, the patent holder has the right to prevent the importation of the patented product.

A remarkable point, which arises from this case, is that a compulsory licence is an isolated action of the State to provide goods to its market, as *e.g.* foodstuffs and medicines, available at the lowest price on grounds of national policies. If it was possible to allow the holder of a compulsory licence to export those goods to another Member State, the establishment of the patent system in the Community would be threatened. Gormley, commenting on this case, stated that "[a] compulsory licence to exploit a patented product or process in one Member State is not a carte blanche to ignore patents in other Member States" and, "... to give 'extra-territorial' effect to patent licences would encourage freeloading by the industry of certain Member States

[39]Note 37, *supra*, [1985] ECR. at p. 2287.
[40]*Ibid.*, at p. 2290.

on the backs of the inventiveness of others"[41]. The CPC, although not yet in force, excludes expressly the application of the principle of exhaustion of patent rights under the grant of a compulsory licence[42].

The Court, analysing the question raised by the Dutch Court, stated that no such "consent" exists in a case of the granting of a compulsory licence:

> In the first place, it is contended that the nature of a compulsory licence is different to that of a licence freely granted because, ..., there are no real negotiations between the compulsory licence and the patentee, ..., and the relationship which in normal circumstances exists between a patentee and a contractual licensee is lacking.
>
> Secondly, it is argued that the objectives of a compulsory licence and a licence freely granted are different. Whilst a licence freely granted is a means of exploitation which goes to the specific subject-matter of the patent right as defined by the Court, a compulsory licence, on the other hand, is essentially intended to meet the special needs of a Member State.
>
> Thirdly, all the abovementioned observations emphasise in particular the "lack of direct or indirect consent" on the part of the patent proprietor in the case of compulsory licences.[43]

The Court finally held, in accordance with the opinion of Advocate-General Mancini, that when a compulsory licence is granted the principle of exhaustion of rights does not apply, because the specific subject-matter was not secured and hence the proprietor of the patent right may prevent the importation of his product.[44]

---

[41]**Laurence Gormley**, Recent Cases on Article 30-36 EEC, [1985] 10 *EL Rev.* 431-457, at 449.
[42]CPC, Art. 81 (3).
[43]Note 39, *supra*, at p. 2296, paras. 18, 19 and 20, respectively. Emphasis added.
[44]See, also, Case 434/85 ***Allen and Hanburys* v. *Generics*** [1988] ECR 1245, [1988] 1 CMLR 701, and Commission's comment on the Court's ruling of Case 19/84 ***Pharmon* v. *Hoechst***, note 37, *supra*, in **Commission of the European Communities**, Fifteenth Report on Competition Policy, Brussels & Luxembourg (1986), pp. 111-112. The case mentioned above in note 36, ***Merck & Co. Inc and others* v. *Primecrown Ltd and others***, may also lead the European Court of Justice to review the application of this principle established in ***Pharmon* v. *Hoechst***. Justice Jacob explicitly affirms that: "The result of all this, says the plaintiffs, is that either the rule in ***Merck* v. *Stephar*** should be changed altogether or qualified. It could be changed, for instance, by reverting back to the notion of exhaustion at least in the case where protection could not be obtained in a particular Member State. Or it could be qualified so that where there is a genuine ethical obligation or a genuine legal

2. THE COMMON RULES ON COMPETITION

The main provisions of the Treaty regarding "the institution of a system ensuring that competition in the common market is not distorted"[45] are Articles 85 to 94. The rules on "dumping"[46] and "aids granted by States"[47] are outside the scope of this work. This section will study only the rules contained in Articles 85 and 86.

To ensure the principle established by Article 3 (g), Articles 85 and 86 of the Treaty prohibit certain types of business practice. These prohibitions have "direct effect"[48] and will be imposed by both the national courts and the Commission. The holder of a patent right is not by that fact alone infringing the rules of the Treaty. He may only be capable of infringing Articles 85 and 86 when these rights are exercised.[49]

2.1. Analysis of Article 85

The structure of Article 85 of the Treaty is based on three paragraphs. Paragraph 1 prohibits "all agreements between undertakings, decision by associations of undertakings and concerted practices which may affect trade between Member

---

obligation upon a party to sell his product in a particular Member State where he has no patent, the goods so sold should not be regarded as put on the market with his consent. The analogy is with goods sold under compulsory licence, which are not so regarded, even though the patentee does receive a royalty, ..." (***Merck & Co. Inc and others* v. *Primecrown Ltd and others***, [1995] *Fleet Street Reports*, p. 914).

[45]EC Treaty, Art. 3 (f).

[46]*Ibid.*, Art. 91.

[47]*Ibid.*, Arts. 92 to 94.

[48]The doctrine of "direct effect" of Community law was first developed by the European Court of Justice in Case 26/62 ***Van Gend en Loos* v. *Nederlandse Tarief Commissie*** [1963] ECR 1, [1963] 1 CMLR 105, when the Court understood that, under certain specific conditions, Community law is capable of establishing rights and obligations which can be enforceable before national courts. See, also, Case 127/73 ***Belgische Radio en Televisie* v. *Sabam*** [1974] ECR 313, [1974] 2 CMLR 238 and Case 148/78 ***Publico Ministero* v. *Ratti*** [1979] ECR 1629, [1980] 1 CMLR 96.

[49]See, in this Chapter, Section 1, Sub-section 1.1, *supra*, for further discussion on the development of the distinction between the existence and the exercise of intellectual property rights.

States".[50] For the purpose of this prohibition the agreements or restrictive practices shall have "... as their object or effect the prevention, restriction or distortion of competition within the common market". Further, Article 85 (1) lists examples of such practices as, *inter alia*, price fixing, limitation of production and sharing markets.

To infringe Article 85 (1), an agreement has to fulfil all the following requirements. There must be an agreement, decision or concerted practice between at least two undertakings, and this must affect trade between at least two Member States. Also, it has to have the object or effect of preventing, restricting or distorting competition within the Common Market. If one of these requirements is lacking, there is no breach of Article 85 (1)[51]. This Article applies to undertakings in the public and private sphere. The meaning of an agreement, under the wording of Article 85, is to be defined in a very wide way, including either written or oral agreements[52].

Furthermore, any agreement or business practice has to be judged in the context of the relevant market. The Commission expressed its view regarding this subject with the publication in 1986 of the "Notice on Agreements of Minor Importance"[53]. The relevant market may be understood as (i) the "relevant product or service market" which "... includes any products or services which are identical or

---

[50]The concept of the word "undertaking" for the meaning of the provisions of the Treaty covers, as stated by **David A.O. Edward & Robert C. Lane**, note 3, *supra*, p. 105, para. 226, "... every type of entity, regardless of its legal status, from a single individual to a multinational corporation, provided he or it has legal capacity and is engaged in economic activity of some sort".

[51]In addition, the Court has ruled in several cases that may not be against the prohibition of Article 85 (1) of the EC Treaty "... where it constitutes no real threat to competition or to the functioning of the common market and where its anticompetitive effects are a necessary incident of the proper functioning of an agreement which is not, in essence, anticompetitive" (**David A.O. Edward & Robert C. Lane**, note 3, *supra*, pp. 107-108, para. 232). This is the so-called "rule of reason" concept which has been reaffirmed by the Court in several decisions, such as in Case 56/65 ***Société Technique* v. *Maschinenbau Ulm*** [1966] ECR 235, [1966] CMLR 357.

[52]The Commission elaborated the concept of an "agreement", for the purposes of Article 85, EC Treaty, quite broadly. See, *e.g.* ***Re the Franco-Japanese Ballbearings Agreement*** OJ 1974 L343/19, [1975] 1 CMLR D8.

equivalent to those [products or services] in question"[54], being "interchangeable" and "substitutable"; and (ii) the "relevant geographic market" which "... is defined by reference to a geographic territory throughout which the product or service in question moves freely"[55].

Article 85 (2) establishes that all decisions or agreements that fall under the prohibition of paragraph 1 "shall be automatically void". It is possible for an agreement to be declared only partially void by the Commission. If the clauses of the agreement which are infringing Article 85 (1) do not affect the agreement as a whole, the Commission will declare void only the clauses in question.

Finally, paragraph 3 of the Article 85 of the Treaty establishes the possibility for an agreement to be "exempted" if it contributes to improve "... the production or distribution of goods ..." or to promote "... technical and economic progress, while allowing consumers a fair share of the resulting benefits, ...". To obtain the exemption an agreement or decision must satisfy all the criteria mentioned above and must not "impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives"[56], and must not "afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question"[57]. The decision about exempting a restrictive agreement will be taken by the Commission[58].

An agreement for the licensing of a patented product, that it can be manufactured and/or sold, may, in some circumstances, infringe the Community rules

---

[53]OJ 1986 C231/2.
[54]**David A.O. Edward & Robert C. Lane**, note 3, *supra*, p. 106, para. 231.
[55]*Ibid.*
[56]EC Treaty, Art. 85 (3) (a).
[57]*Ibid.*, Art. 85 (3) (b).

on competition. However, it is possible to apply for the granting of an exemption pursuant Article 85 (3) of the Treaty, Regulation 17 and Regulation 240/96. Also, if one or more clauses of the agreement infringes Article 85 (1) it may be declared void by the Commission.

2.1.1. Article 85 and patent licensing agreements

As has been seen above, only the existence of an intellectual property right is protected by the Treaty. Its exercise may infringe the provisions on the free movement of goods and competition. Concerning patent protection, the most important discussions have been on licensing agreements. The Commission itself, on 24 December 1962, published a "Notice on Patent Licensing Agreements" (the "Christmas Message")[59] expressing its views and clarifying the interpretation of the application of Article 85 in this field. At this time, the Commission took an opportunity to affirm that most of the clauses of a patent licensing agreement would not infringe Article 85 (1), since the restrictions imposed on a licensee represented a natural position of the licensor emanating from the latter's monopoly. However, this view could not be maintained. A few years later the Court of Justice, in a case related to trade-mark rights[60], explicitly understood that the exercise of an intellectual property right will in some ways infringe the Community rules on competition.

A patent licensing agreement[61] is essentially the granting, by the holder of an intellectual property right, of permission for a third party to exploit the right against

---

[58]Regulation 17, Arts. 4 to 9.
[59]OJ, Special Edition, 1962 C139/2922. This notice was later withdrawn (OJ 1984 C220/14).
[60]Joined Cases 56 & 58/64 ***Consten & Grundig v. Commission***, note 12, *supra*.
[61]Regulation 240/96, in the Preamble, Recital (5), provides the following definition of patent and know-how licensing agreements: "Patent or know-how licensing agreements are agreements whereby

the respective payment of royalties. This exploitation may be for manufacturing, selling, or both. The European Court of Justice recognised that the exploitation of a patent through licences constitutes the specific subject-matter of the right. However, questions related to the applicability of Article 85 (1) of the Treaty arise if there are included in the licensing agreement terms that go beyond the meaning of the specific subject-matter of the intellectual property right, or where the exercise of such a right has the means, the object or the consequence of a restrictive agreement.[62] This problem emerges when one party of the agreement, either the licensor or the licensee, imposes restrictions on the activity of the other party. Some of these restrictions are understood as being within the specific subject-matter of the patent right, and, thereby, not breaching the rules of the Treaty. However, some of them will infringe Article 85 (1). Therefore, two specific issues must be analysed on a patent licensing agreement: first, whether the licence is caught by Article 85 (1) of the Treaty and, if caught, whether or not the agreement will be qualified for individual or block exemption under Article 85 (3).

In addition, an agreement will not infringe Article 85 (1) - even if it has the object of preventing, restricting or distorting competition - when it is considered of minor importance. The "de minimis" doctrine emerges from the Commission's Notice on Agreement of Minor Importance[63] and is seen as a weak position. Whish, commenting on the problems which arises from the application of this doctrine, stated:

---

one undertaking which holds a patent or know-how ('the licensor') permits another undertaking ('the licensee') to exploit the patent thereby licensed, or communicates the know-how to it, in particular for the purposes of manufacture, use or putting on the market".

[62]See, *e.g.*, Case 40/70 ***Sirena* v. *Eda***, note 12, *supra*.

[63]Note 53, *supra*.

> Article 85 (1) will not apply where an agreement is one of minor importance. The problem with the "de minimis" doctrine in patent licence is that a successful exploitation of the patent is likely to increase the parties' turnover and market share and take them above the relevant thresholds. This would presumably mean that the agreement outgrows the "de minimis" rule and comes within Article 85 (1). Article 85 (1) will not apply to an agreement which is incapable of affecting inter-state trade. Assuming that these requirements are satisfied, various terms in the licence may be considered to infringe Article 85 (1).[64]

The Commission, using the power conferred by the Treaty, and by Regulation 17, analyses the patent licensing agreement and the provisions that it contains. The undertaking, or the parties involved in an agreement, shall notify the Commission or apply for an individual or block exemption pursuant Article 85 (3) and Regulation 240/96. In case the Commission is not favourable to the agreement the undertaking can appeal from the decision of the Commission to the Court of First Instance[65] which is entitled to review the Commission's decision.

The Commission analyses an agreement case by case. The Regulation 240/96 lists provisions that may be exempted and provisions which fall within Article 85 (1). However, this Regulation does not exhaust all the circumstances of patent licensing agreements. An analysis of each provision may be necessary. Provisions such as vertical price fixing[66] will come within Article 85 (1). Other provisions, such as

---

[64]**Richard Whish,** Competition Law. London: Butterworth and Co. (Publishers) Ltd. (1989) 2nd ed., pp. 660-661.

[65]**David A.O. Edward & Robert C. Lane**, *supra*, note 3, at p. 29, para. 84, provides the following explanation of the establishment of the Court of First Instance: "In order to ease the workload of the Court of Justice the Single European Act amended the founding treaties so as to empower the Council, upon a request from the Court of Justice, to 'attach' to it a court with first instance jurisdiction in certain forms of action" (EC Treaty, Art. 168a). The Court of First Instance shall "... hear and determine at first instance, ... certain classes of actions or proceeding ..." but "... shall not be competent to hear and determine questions referred for a preliminary ruling under Article 177" (*Ibid.*, Art. 168a (1)).

[66]Regulation 240/96, Art. 3 (1).

obligations of secrecy[67], to prevent infringements of the patent[68] and most-favoured licensee clauses[69], will all be capable of exemptions. Below, the most important clauses of patent licensing agreements are analysed.

(a) Open exclusive licence and absolute territorial protection

Patent licensing agreements usually include provisions imposing an obligation upon the licensor not to grant licences to other undertakings in the licensed territory or not to exploit the patent himself in the licensed territory. This has been a controversial field of discussion since the very beginning of the establishment of the rules of the Community. When the Commission published the "Christmas Message"[70] its view was very liberal. Throughout the development of this discussion the Commission took a more restricted approach when in certain decisions taken in 1972[71] the Commission looked at exclusive licences as falling within the prohibitions of Article 85 (1). Later, the Commission developed this point in several other decisions[72].

A distinction, however, was elaborated by the European Court of Justice concerning exclusive agreements. Under an "open exclusive licence" - *i.e.* a licence that does not grant absolute territorial protection - the licensor agrees not to grant a licence to other undertakings and not to manufacture or market the protected product himself within the licensed territory. The market, however, in the licensed territory

---

[67] *Ibid.*, Art. 2 (1) (1).
[68] *Ibid.*, Art. 2 (1) (6).
[69] *Ibid.*, Art. 2 (1) (10).
[70] Note 59, *supra*.
[71] ***Burroughs/Delplanque*** OJ 1972 L13/50, [1974] CMLR D67 and ***Davidson Rubber*** OJ 1972 L143/31, [1974] CMLR D52.
[72] See, *e.g.*, Commission's decisions on the following patent agreements: ***AOIP/Beyrard*** OJ 1976 L6/8, [1976] 1 CMLR D14; ***Kabelmetal/Luchaire*** OJ 1975 L222/34, [1975] 2 CMLR D40; ***Bronbemaling/Heidemaatschapij*** OJ 1975 L249/27, [1975] 2 CMLR D67; ***Video Cassette***

remains open to parallel importers, even to other licensees of the same product in other territories of the Community. The Court, in the so-called ***Maize seeds case***[73], held that such an arrangement will not fall within Article 85 (1). In this case the Court accepted the view that the grant of an "open exclusive licence" is capable of promoting technical progress[74]. From the decision taken in the ***Maize seeds*** case a question which arises is if the interpretation applies equally to other form of intellectual property rights, including patents. According to Bellamy and Child "... it seems that the reasoning in ***Nungesser*** is fully applicable to other intellectual property rights, particularly patents"[75].

What emerges from this case is that the Treaty does not allow the licensee to impose "absolute territorial protection", but some limited type of exclusivity is allowed on grounds of technological progress. The Court held, then, that "absolute territorial protection granted to a licensee in order to enable parallel imports to be controlled and prevented results in the artificial maintenance of separate national markets, contrary to the Treaty"[76].[77]

Recorders OJ 1978 L47/42, [1978] 2 CMLR 160; ***Vaessen Morris*** OJ 1979 L19/32, [1979] 1 CMLR 511.

[73]Case 258/78 ***Nungesser v. Commission*** [1982] ECR 2015, [1983] 1 CMLR 278.

[74]*Ibid.*, [1982] ECR at p. 2069, para. 55.

[75]**Vivien Rose**, note 14, *supra*, at p. 548.

[76]Note 74, *supra*, at p. 2070, para. 61.

[77]See, for a more detailed discussion on this subject, **Vivien Rose**, note 14, *supra*, pp. 545-549; **Dieter Hoffmann & Orlagh O'Farrel** The 'Open Exclusive Licence' - Scope and Consequences, [1984] 4 *EIPR* 104-110; and Korah's criticism to the latter's position in [1984] 6 *EIPR* 206. For more recent decisions, see ***Tetra Pak I (BTG Licence)*** OJ 1988 L272/77, appeal case before the Court of First Instance Case T-51/89 ***Tetra Pak v. Commission*** note 8, *supra*; ***Rich Products/Jus-rol*** OJ 1988 L69/21, [1988] 4 CMLR 527, and; ***Delta Chemie/DDD*** OJ 1988 L309/34, [1989] 4 CMLR 535. See, also, Regulation 240/96, Art. 1 (1) (1), (2), (3), (4) and (6).

(b) Tie-in and quality obligations

A tie-in obligation is imposed upon the licensee (s) and is a clause in an agreement requiring the latter to buy a second product, as a complementary material, or services from the licensor only or from an undertaking designated by the licensor. Under Regulation 240/96 this clause will not infringe Article 85 (1) "... in so far as these quality specifications are necessary for: (a) a technically proper exploitation of the licensed technology; or (b) ensuring that the product of the licensee conforms to the minimum quality specifications that are applicable to the licensor and other licensees; and to allow the licensor to carry out related checks"[78]. A controversial discussion has taken place in relation to this clause as far as a tie-in obligation is mentioned in Article 85 (1) (e) of the Treaty among the list of clauses that restrict competition within the Community.

The first time that the Commission rejected a tie-in clause was in its decision in ***Vaessen/Morris***[79]. The purpose of a tie-in obligation is to "secure the fullest technical and economic exploitation of the licensed invention"[80]. Under Regulation 2349/84 it was explicit that if there was an obligation with the purpose of imposing on the licensee trade for complementary products or services that are not directly related with the patented product or process, it would fall within the prohibition of Article 85

[78]Regulation 240/96, Art. 2 (1) (5).

[79]Note 72, *supra*. The Commission has, nevertheless, accepted a tie-in clause in decision ***Re Campari*** OJ 1978 L70/69, [1978] 2 CMLR 397, on grounds of the protection of a trade secret. For a critical view on the Commission's decision in ***Vaessen/Morris*** see **L. Zanon**, Ties in Patent Licensing Agreements, [1980] 5 *EL Rev*, 391-399.

[80]**Noel Byrne**, Patent Tie-in Arrangements and Article 85, [1980] *EIPR* 141-148, p. 146.

(1)[81]. Although Regulation 240/96 does not include such a prohibition it seems that this would be decided on a case-by-case basis by the Commission.

It is also worth noting that under Regulation 2349/84, an obligation on the licensee to manufacture the licensed product to a minimum standard of quality would not breach Article 85 (1), by virtue of Article 2 (9), if it was necessary for a "... technically satisfactory exploitation of the licensed product".

Regulation 240/96 recognised a relationship between tie-in and quality obligations and merged both provisions of Regulation 2349/84 into one single provision of Regulation 240/96, by accepting that both clauses in a licensing agreement are connected by the need of a technically satisfactory exploitation of the technology, ensuring that the product of the licensee conforms to minimum quality specifications.

Finally, it is also necessary to mention that if the licensor imposes on the licensee a "quality" and a "tie-in" obligation which are not necessary for a technically satisfactory exploitation of the licensed technology, but notifies the Commission and the latter does not oppose such exemption in a period of four months, such a clause will not be deemed as falling within Article 85 (1) of the Treaty.[82]

(c) Restriction on the field of use

A field of use clause intends to restrict the licensed invention to be exploited in one or more ways. Generally this clause does not fall within Article 85 (1)[83] of the Treaty if the results of an agreement are not aimed to restrict competition between the licensees

---

[81]Regulation 2349/84. Art. 3 (9).
[82]Regulation 240/96. Arts. 4 (1) and 4 (2) (a).

or between the parties of the agreement in question, "... since the licensor is entitled to transfer the technology only for a limited purpose"[84] [85]

In the case of ***Windsurfing International* v. *Commission***[86], for example, the Court, following the Commission's arguments, condemned a provision in the agreement imposing upon the licensee the use of a windsurfer rig[87] only in certain types of boats. The Court held that the licensor, in this case, had interest essentially "... in ensuring that there was sufficient product differentiation between its licensees' sailboards to cover the widest possible spectrum of market demand"[88] and, therefore, its object was the distortion of competition within the Community. The Court, however, may accept the field of use restriction "... only if related to different products belonging to different markets"[89].

(d) No-challenge clauses

A no-challenge clause is an obligation on the licensee not to challenge the validity of the patent right of the licensed product. This clause can be seen in two ways: as a part of the licence agreement or as a part of a settlement of patent disputes. In the first case the justification is that the transfer of information involved in a licence permits

---

[83] *Ibid.*, Art. 2 (1) (8).
[84] *Ibid.*, Recital (22).
[85] See **Commission of the European Communities**. Fourth Report on Competition Policy. Brussels. Luxembourg (1975). p. 22. for Commission's view.
[86] Case 193/83 [1986] ECR 611. [1986] CMLR 489.
[87] *Ibid.*, for the definition of a "rig", [1986] ECR 611. at p. 645. para. 2.
[88] *Ibid.*, at p. 656. para. 49.
[89] *Ibid.*, at p. 654. para. 42.

the licensee to acquire knowledge and consequently challenge it. In the second case, however, it is justified on grounds of public policy.[90]

Such a clause, the Court held, in accordance with other decisions of the Commission[91], does not come within the specific subject-matter of a patent.[92] Consequently, a no-challenge clause was normally caught by the prohibition of Article 85 (1).[93] In ***Raymond/Nagoya***[94], the Commission took the view that such a no-challenge clause was a restriction on the licensee's freedom of action which, accordingly to the Court's view in the above-mentioned ***Windsurfing International*** case, does not constitute the specific object of a patent right.

Later, nevertheless, in conflict with the Commission's argument, the Court held in ***Bayer* v. *Sülhofer***[95] that a no-challenge clause, when part of a settlement agreement, was not capable of exemption under Article 85 (3). The Court here appears to have "... stepped back from the ***Windsurfing*** case. As a result, every no-challenge clause must be individually considered in its context and the public interest test is ignored"[96], in accordance with the obligations laid down by Regulation 2349/84.

Regulation 240/96, on the other hand, did not exclude the possibility of a no-challenge clause to be exempted under the block exemptions mechanism. In this case,

---

[90]See Commission's argument in Case 65/86 ***Bayer* v. *Sülhofer*** [1988] ECR 5249, [1990] 4 CMLR 182, at [1988] ECR pp. 5257-5258. See, also, a more detailed discussion in **John Ferry**, Patents Agreements: No-challenge Clauses, [1989] 4 *EIPR* 138-139.

[91]The first occasion that the Commission held that a no-challenge clause falls within Article 85 (1) was in ***Burroughs/Geha*** OJ 1972 L13/53, [1972] 4 CMLR D72. The Commission's approach was quite strict and in agreements such as ***Davidson Rubber***, note 71, *supra*, and ***Kabelmetal/Luchaire***, note 72, *supra*, it compelled removal of the clauses.

[92]See Case 193/83, note 86, *supra*.

[93]Regulation 2349/84, Arts. 2 (1) (8) and 3 (1).

[94]OJ 1972 L143/39, [1972] CMLR D45.

[95]Case 65/86, note 90, *supra*.

[96]**John Ferry**, note 90, *supra*, p. 139.

however, a different legal situation was described. Article 2 (1) (15) of the Regulation 240/96 states that it is generally no restriction to competition, and thus not falling within the prohibition of Article 85 (1) of the Treaty, "a reservation by the licensor of the right to terminate the agreement if the licensee ... challenges the validity of licensed patents within the common market belonging to the licensor or undertakings connected with him"[97].

(e) Non-competition clauses

A provision in a patent licensing agreement with the obligation on the licensee not to manufacture, use or sell competing products normally falls within Article 85 (1).[98] The Commission itself expressed its view when it said:

> Non-competition prohibitions can have the effect of not only strengthening a monopoly position of a patentee, but also of weakening competition between manufacturers of substitute products. A licensee might no longer have worthwhile prospects in carrying out independent development. Accordingly, the Commission regards non-competition provisions as covered by Article 85 (1). Possibilities of exemption under Article 85 (3) could only arise in special situation, particularly cases relating to specialization agreements.[99]

As it can be understood from the above-mentioned points, an obligation on the licensee not to work on the development of new products that would compete with the licensed product also falls within Article 85 (1), EC Treaty.[100] However, in a later

---

[97] See. also. Regulation 240/96. Art. 4 (2) (b).
[98] See. *e.g.* Commission's decision in ***Maize seeds*** OJ 1978 L286. [1978] 3 CMLR 434. and ***Windsurfing International v. Commission***. note 86 , *supra*. See. also. Regulation 240/96. Art. 3 (2).
[99] **Commission of the European Communities**. note 85. *supra*. p. 23.
[100] *Ibid.*. See. also. ***AOIP/Beyrard*** OJ 1976 L6/8. [1976] 1 CMLR D14 at D24.

decision, ***Delta Chemie/DDD***[101], it was held that an obligation imposed on the licensee not to manufacture, use or sell competing products without the licensor's consent was not contravening Article 85 (1).

The licensor is nevertheless authorised by Regulation 240/96, Article 2 (1) (18), to make a reservation in the agreement of the right to terminate the exclusivity granted to the licensee if the latter enters into competition within the Common Market with the licensor or with undertakings connected with him, and to require the licensee to prove that the licensed know-how is not being used for the production of products and the provision of services other than those licensed. This provision seems to be necessary to guarantee the application of the provisions listed in Article 1 (1) of the Regulation 240/96.

(f) Grant-back clauses

The so called "grant-back" clauses are related to an obligation on the licensee or the licensor to inform the other party about any improvements on the licensed product and to "grant-back" a licence in respect to any invention which comes from the improvements in question. Under Article 2 (1) (4) of Regulation 240/96 there is no restriction of competition, provided that the licensor is put under a corresponding obligation, and the licences to be granted by either party are non exclusive "... so that the licensee is free to use his own improvements or to license them to third parties, in so far as it does not involve disclosure of the know-how communicated by the licensor that is still secret, and that the licensor undertakes to grant an exclusive or

[101] Note 77, *supra*. Although this case is related with know-how and trade-mark licensing, it seems to apply also to pure patent and mixed licensing agreements.

non-exclusive licence of his own improvements to the licensee"[102] However, this clause will fall within Article 85 (1) if one of the parties is required to assign the property of the inventions exclusively to the other[103, 104]

(g) Royalties

The obligation on the licensee to pay royalties to the licensor is clearly within the specific subject-matter of the patent right, in so far as it signifies the recompense for the creative effort of the inventor and the right to exploit commercially the patented product. However, some obligations concerning the payment of royalties will fall within the prohibition of Article 85 (1).

In the context of clauses concerning the payment of royalties, two specific situations should be analysed. The first is when there is an obligation for the payment of minimum royalties. Under Regulation 240/96[105] this provision is not a restrictive clause because it ensures the adequate exploitation of the product in question.

The second case is related to an obligation on the licensee to pay royalties after the expiry of a patent or after the expiry of the licensing agreement. An obligation on the licensee to continue paying royalties after the expiry of the patent will generally fall within Article 85 (1)[106]. However, if the payment of the royalty is related to a know-how that is still being used by the licensee and has been made

---

[102]Regulation 240/96, Art. 2 (1) (4). See also **Derrick Wyatt & Alan Dashwood**. The Substantive Law of the EEC. London: Sweet & Maxwell (1987) 2nd ed., at p. 508, and Commission's decision in ***Davidson Rubber*** agreement, note 71, *supra*.

[103]*Ibid.*, Art. 3 (6). See, also, ***Raymond/Nagoya***, note 94, *supra*, and ***Kabelmetal/Luchaire***, note 72, *supra*. The same prohibition applies to the obligation on the licensee to grant to the licensor joint ownership of the invention (***Nodet/Lamazou***, in **Commission of the European Communities**. Tenth Report on Competition Policy. Brussels, Luxembourg (1981), p. 88, para. 127).

[104]See, also, Regulation 240/96, Recital (20).

[105]Regulation 240/96, Art. 2 (1) (9).

publicly by the licensee himself, an exemption may be granted[107]. Regulation 240/96 also accepts, in Article 2 (1) (7) (b), that the licensee continues to pay the royalties to the licensor after the expiry of the licensing agreement "... in order to facilitate payment"[108, 109]

(h) Duration clauses

Article 3 (7) of the Regulation 240/96 prohibits an obligation imposed upon the licensor, through a separate agreement or through a clause in the licensing agreement, extending the duration of the agreement by the inclusion of any new improvements. Such prohibition is concerned with the exploitation of the licensed technology in the territory exploited by other licensees or by the licensor himself, including the imposition of limits for parallel importation, and shall not exceed five years, in case of pure patent licensing agreements, and ten years, in case of either pure know-how licensing agreements or mixed patent and know-how licensing agreements.[110]

---

[106]***AOIP/Beyrard***, note 100, *supra*.

[107]See Regulation 240/96, Art. 2 (1) (7) (a). Note, in addition, that such an exemption is without prejudice to the payment of additional damages in the event of the know-how being made publicly by the licensee or as a consequence of his action.

[108]See, also, Regulation 240/96, Recital (21) which affirms that "... the parties must be free, in order to facilitate payment, to spread the royalty payment for the use of the licensed technology over a period extending beyond the duration of the licensed patents, in particular by setting lower royalty rates".

[109]When Regulation 2349/84 was in effect, an additional situation was predicted where exemption could not be granted. This was an obligation on the licensee to pay royalties on products not entirely or partially patented. It was understood that this had the object of discouraging the licensee to supply different products separately (Regulation 2349/84, Art. 3 (4)).

[110]*Cf.* Regulation 240/96, Art. 1(2), (3) and (4). Article 1 of the Regulation 240/96 will be further described in Paragraph 2.1.2, Sub-paragraph (b), *infra*.

Exemption may be granted only by individual decision for longer periods of territorial protection, particularly to protect "... expensive and risky investment or where the parties were not competitors at the date of the grant of the licence"[111].

(i) Output restrictions

Restrictions imposed on the licensee regarding the quantity of products manufactured shall be analysed under two views. Firstly, a provision which establishes an obligation of producing a minimum quantity of the licensed product will not fall within Article 85 (1)[112]. Such a provision is considered necessary to ensure the adequate exploitation of the product in question[113]. In contrast, a clause imposing on the licensee the obligation to produce a maximum quantity of the licensed product will fall within Article 85 (1). The Commission's view is that such provision makes the licensee weaker as a competitor and, if imposed on a number of licensees, it may have a similar effect to an export ban[114].

(j) Price restrictions

Restrictions on prices are prohibited by Article 3 (1) of Regulation 240/96. Thus, an obligation on the licensee or the licensor "... in the determination of prices, components of prices or discounts for the licensed product" fall within Article 85 (1).[115]

---

[111]Regulation 240/96, Recital (14).
[112]*Ibid.*, Art. 2 (1) (9).
[113]See, *e.g.*, ***Burroughs/Delplanque***, note 71, *supra*.
[114]**Commission of the European Communities**, Ninth Report on Competition Policy, Brussels, Luxembourg (1980), p. 22.
[115]See, also, Regulation 240/96, Recital (24).

(k) Customer restrictions

An obligation on the licensee or on the licensor as to the customers he may serve, or restrictions on the form the licensed product will be distributed, or "...with the aim of sharing customers, using certain types of packaging for the products"[116] falls within Article 85 (1) and is not capable of exemption. In contrast, an obligation on the licensee to supply only a limited quantity of the licensed product to a particular customer, where the licence was granted so that the customer might have a second source of supply inside the licensed territory will not fall within the prohibition of Article 85 (1) of the Treaty[117, 118].

(l) Export restrictions

An export restriction imposed on the licensee clearly infringes Article 85 (1). It has already been seen that any restriction to the free movement of goods within the Community is contrary to Articles 30 to 36 of the Treaty. The Commission expressed its view affirming that export bans within the Community "... are contrary to the very idea of a single market and are as a matter of principle caught by Article 85 (1)" and, further, it affirmed that it may accept some exceptions "... under certain tightly defined conditions, notably in favour of small and medium-sized businesses"[119].

---

[116]Regulation 240/96. Art. 3 (4). See. also. Recital (17).

[117]*Ibid.*. Art. 2 (1) (13). This applies also to the licensee where the latter is the customer "... and the licence was granted in order to provide a second source of supply provides that the customer is himself to manufacture the licensed products or to have them manufactured by a subcontractor" (*Ibid.*).

[118]See. also. Regulation 240/96. Recital (23).

[119]**Commission of the European Communities**. note 114. *supra*. p. 22. Note. however. that the licensor may make a reservation in connection with his right "... to exercise the rights conferred by a patent to oppose the exploitation of the technology by the licensee outside the licensed territory"

(m) Most favoured licensee clause

An obligation imposed on the licensor to grant to the licensee more favourable terms than to other licensees is capable of exemption under Regulation 240/96.[120] In ***Kabelmetal/Luchaire***[121], however, the Commission found that a clause in most favourable terms was restricting competition within the Community.

(n) Assignments and sub-licences

Restrictions on the licensee not to assign or grant sub-licences does not fall within the prohibitions of Article 85 (1)[122]. However, "the exercise of the right deriving therefrom may be limited by the rules of the Treaty"[123], depending on "the turnover attained by the assignee in respect of products made using the know-how or the patents, the quantity of such products manufactured or the number of operations carried out employing the know-how of the patents". This applies when the risk associated with exploitation remains with the assignor[124].

(Regulation 240/96. Art. 2 (1) (14)). and may also impose an obligation on the licensee not to use or manufacture the licensed product. or use the licensed process. in territory of the licensor or in territories in the Common Market which are licensed to other licensees (*Ibid.*. Art. 1 (1) (3) and (4). and Recital (11)).

[120]Regulation 240/96. Art. 2 (1) (10).

[121]Note 72. *supra*.

[122]Regulation 240/96. Art. 2 (1) (2).

[123]**Vivien Rose**. note 14. *supra*. at p. 559.

[124]Regulation 240/96. Art. 6 (2) and Recital (9).

(o) Restrictions on patent licence for non-Member State

The Commission faced the problem for the first time in an agreement between Raymond, a German company, and Nagoya, a Japanese company.[125] In this agreement, Raymond granted a licence to Nagoya in respect of a plastic product used in the construction of cars. The licence contained a limitation on exports to the Community. The Commission understood that such a product could be obtained in the Community without difficulty by the licensor and by other companies and, consequently, such an agreement was not infringing the rules of the Treaty. It is also noteworthy that Regulation 240/96 applies equally to agreements involving non-Member States, particularly when such licensing agreements "... have effects within the common market which may fall within the scope of Article 85 (1), ..."[126].

2.1.2. Article 85 (3) - block exemptions

The Commission is empowered by Article 85 (3) of the Treaty to grant individual and "block exemptions" to individual and categories of agreements, respectively. Under Regulation 17, Article 24, the Commission was given legislative powers and functions to implement provisions regarding procedural matters. Under Regulation 19/65[127] the Council of the European Communities authorised the Commission to enact Regulations providing group exemptions for categories of agreements between two

---

[125] ***Raymond/Nagoya***, note 94, *supra*.

[126] See Recital (7) of the Regulation 240/96. See, also, ***BBC/Brown Boveri*** OJ 1988 L301/68, [1988] 4 CMLR 427, where the Commission held that an exclusive licence granted to a Japanese company was infringing Article 85 (1) of the Treaty, because the exports to the Community would be affected with such agreement.

[127] OJ, Special Edition, 1965-1966, 35, 1965, 533.

undertakings covering, *inter alia*, patent licences and "... a method of manufacture or knowledge relating to the use or to the application of industrial processes"[128].

When the Commission grants an individual exemption it takes into account, as seen above, whether the agreement in question "... contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit"[129], and whether the agreement does not impose restrictions on the undertaking concerned "... which are not indispensable to the attainment of these objectives"[130] and whether the agreement does not "afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question"[131]. The Commission, when it enacts a Regulation on group exemptions, takes into account all the requirements above-mentioned.

In order to improve the legal mechanisms of the Community, group exemptions must have a time limit. Through the experience obtained during the life of a Regulation, changes can be proposed or the original text can be maintained. Both Regulation 2349/84, concerning the application of Article 85 (3) for patent licensing agreements, and Regulation 556/89, concerning the application of Article 85 (3) for know-how licensing agreements, were considered to apply for a period of ten years.[132]

---

[128]Regulation 19/65, Art. 1 (1) (b).
[129]EC Treaty, Art. 85 (3).
[130]*Ibid.*, Art. 85 (3) (a).
[131]*Ibid.*, Art. 85 (3) (b).
[132]Regulation 19/65, Art. 2 (1), note 127, *supra*, states that such Regulations "shall be made for a specified period". Art. 14, Regulation 2349/84, establishes that it will enter into force from 1 January 1985 and will apply until 31 December 1994. Art. 12, Regulation 556/89, establishes that it will enter into force from 1 April 1989 and will apply until 31 December 1999.

Regulation 240/96, which replaces both Regulations 2349/84 and 556/89 entered into force on 1 April 1996 and applies until 31 March 2006[133].

(a) Background on Regulations 2349/84 and 556/89

The Commission, on 23 July 1984, published Regulation 2349/84 on the application of Article 85 (3) of the Treaty to certain categories of patent licensing agreements.[134] This Regulation applied equally to patent agreements and agreements combining the licensing of patent and the communication of know-how. However, the latter did not apply if the know-how in the agreement was the dominant element of it. If it was so, exemption would be granted under Regulation 556/89. Moreover, this Regulation did not apply to agreements between members of a patent pool, agreements in connection with a joint venture, reciprocal licences - unless the agreement did not involve any territorial restriction within the Common Market - and plant breeders' rights[135].

On 4 March 1989 the Commission published the Regulation 556/89 on the application of Article 85 (3) of the Treaty to certain categories of "know-how"[136] licensing agreements[137]. This Regulation applied to know-how agreements and mixed agreements combining the licensing of know-how and the acquisition or use of other

---

[133]Regulation 240/96, Art. 13.

[134]It must be noted that the Commission took nineteen years to enact this Regulation, since it has been empowered to do so by Regulation 19/65, note 127, *supra*.

[135]Regulation 2349/84, Art. 5 and Recital (8). A remarkable point is related to the exclusion of plant breeders' rights from the scope of this Regulation. In ***Nungesser v. Commission***, note 73, *supra*, the Court seemed to have understood that plant breeders' rights were in similar position to patents for competition purposes.

[136]For the purpose of this Regulation "know-how" was defined as "... a body of technical information that is secret, substantial and identified in any appropriate form" (Regulation 556/89, Art. 1 (7) (1)).

[137]The Commission was very much criticised when enacted Regulation 2349/84 for not including the possibility for exemption for pure know-how. Thereafter, the Commission had been seeking actively for opinions of businessmen towards the adoption of Regulation 556/89. For a discussion on the Commission action's towards a Regulation concerning block exemptions for know-how licensing

industrial property rights, if the know-how in the agreement was the dominant part of it. Regulation 556/89 did not apply to agreement between members of a patent or a know-how pool, agreements in connections with a joint venture, reciprocal agreements, and agreements relating to the licensing of other industrial property rights, excluding patents, or the licensing of software, if the patent rights or the software were not of assistance in achieving the object of the licensed technology[138].

The structure of Regulation 556/89 was very similar to that of Regulation 2349/84. It is also important to recall that both Regulations 2349/84 and 556/89 applied only to agreements between two undertakings[139].

(b) The new regulation on technology transfer: Regulation 240/96[140]

Due to the expiration of Regulation 2349/84 on 31 December 1994[141], the Commission started to circulate draft versions of a regulation on certain categories of technology transfer agreements, aiming at replacing and updating Regulation 2349/84 and regulating block exemptions also for know-how licensing agreements[142].

With a view to allowing further discussion of the complex issues approached by the draft regulation on technology transfer agreements, the validation of Regulation 2349/84 was extended until 31 December 1995[143]. A preliminary draft

---

agreements, see **Valentine Korah**, European Commission's Tentative Views on Know-How Licensing, [1986] 12 *EIPR* 79-86.

[138]Regulation 556/89, Art. 5.

[139]Regulation 19/65, Art. 1 (1), Regulation 2349/84, Art. 1 (1), and Regulation 556/89, Art. 1 (1). In a case involving more than two undertakings the possibility still remains under Regulation 17, where it is possible to apply for an individual exemption.

[140]All the provisions mentioned in this Sub-paragraph are related with Regulation 240/96 if no other reference is given.

[141]*Cf.* note 132, *supra*.

[142]Regulation 556/89, on block exemptions for now-how licensing agreements, was due to expire only on 31 December 1999 (*Cf.* note 132, *supra*).

[143]OJ 1995 L214/6.

Commission Regulation (EC) of 30 September 1994 on the application of Article 85 (3) of the Treaty to certain categories of technology transfer agreements was published[144] and further discussion took place. Eventually, the Commission published on 9 February 1996 the "Commission Regulation (EC) N. 240/96 of 31 January 1996 on the application of Article 85 (3) of the Treaty to certain categories of technology transfer agreements"[145].

Regulation 240/96 combines into a single set of rules, block exemptions for "pure" patent[146], "pure" know-how[147] and "mixed"[148] licensing agreements.[149] In general, Regulation 240/96 remains with the same structure as that of Regulations 2349/84 and 556/89, changing, however, substantive concepts related with the application of block exemptions for technology licensing.

Probably the first major change which must be considered more carefully is that Regulation 240/96 put under a single procedure the regulatory measures for block exemptions of pure patents, pure know-how and mixed technology licensing. Under the division provided by Regulations 2349/84 and 556/89 one could choose which Regulation would bring the benefits of block exemptions. So, by virtue of Regulation 240/96, Regulation 556/89 is revoked and replaced by the former. Businessmen who thought that they had norms for know-how licensing valid until the

---

[144]OJ 1994 C178/3 (*corrigendum* OJ 1994 C187/16).
[145]*Cf.* note 2, *supra*.
[146]This applies to Member State's own patents, Community Patents (patents granted under the Convention for the European Patent for the Common Market, discussed in Chapter 4, *infra*) and European Patents (patents granted under the Convention on the Grant of European Patents, discussed in Chapter 4, *infra*).
[147]Such as descriptions of manufacturing processes, recipes, formulae, designs or drawings .
[148]Combined patent and know-how licensing agreements.
[149]Recital (4).

end of 1999[150], will face different legal circumstances brought to life by Regulation 240/96 and which will be further discussed below. This leads to legal uncertainty and more costs for business[151].

The basic structure of Regulation 240/96 is a Preamble with twenty seven Recitals and a framework of thirteen Articles. The provisions of the "white list" of Regulations 2349/84 and 556/89 remain (Article 2), with some extended clauses which will be deemed not restrictive to competition. The "black list" (Article 3) has been shortened on the ground that a "market share"[152] test will apply for assessing licensing behaviour within the Common Market. The provisions of Regulation 240/96 will be discussed in more detail below.

Article 1 exempts several clauses relating to exclusivity and territorial protection which fall within Article 85 (1), applying to exclusive and non-exclusive licences. Article 1 (1) lists the obligations in pure patent, pure know-how or mixed licensing agreements, including agreements containing "ancillary provisions"[153],

---

[150]Note 132, *supra*.

[151]Obviously, the provisions of agreements exempted under Regulations 2349/84 and 556/89, and which keeps satisfying the conditions there established, will be valid, by virtue of Article 11 (3), Regulation 240/96, for agreements in force on 31 March 1996. It is possible to assume, as a matter of interpretation, that agreements under Regulation 556/89 and in force on 31 March 1996, will be valid until 31 December 1999. Those agreements in force on 31 March 1996 and related with patent block exemption will be valid until the date of expiration of the agreement in question or of the patent.

[152]The "licensee's market share" is defined by Regulation 240/96 as "... the proportion which the licensed products and other goods or services provided by the licensee, which are considered by users to be interchangeable or substitutable for the licensed products in view of their characteristics, price and intended use, represent the entire market for the licensed products and all other interchangeable or substitutable goods and services in the common market or in substantial part of it" (Art. 10 (9)).

[153]Article 10 (15) defines "ancillary provisions" as "... provisions relating to the exploitation of intellectual property rights other than patents, which contain no obligations restrictive of competition other than those also attached to the licensed know-how or patents and exempted under this Regulation".

between only two undertakings[154], which do not fall within the prohibition of Article 85 (1) of the Treaty.

Regarding the protection of the licensee, Article 1 (1) (1) exempts restrictions imposed on the licensor not to license other undertakings to exploit the licensed technology[155] within the territory where the licensee is authorised to exploit it. Moreover, the licensee may impose a restriction on the licensor, under Article 1 (1) (2), not to exploit the licensed invention in the licensed territory himself. The term "licensed territory" must be understood as covering all the Common Market or only part of it.[156]

Regarding restrictions imposed on the licensee to protect the licensor, Article 1 (1) (3) exempts an obligation prohibiting the licensee to exploit the licensed technology "... in the territory of the licensor within the common market"[157]. This "reserved territory" must be understood in a very broad way and it includes the areas where the licensor is exploiting the licensed technology himself, as well as the areas where the licensor has not yet granted a licence or has not yet been exploiting the invention himself. The licensor is also authorised, by Article 1 (1) (7), to impose on the licensee an obligation to use "... only the licensor's trademark or get up to

---

[154] *Cf.* note 139, *supra*.
[155] *Cf.* Recital (10).
[156] Where the agreement is a pure patent licensing agreement, these obligations are exempted only for as long as the licensed product is protected by parallel patents in the territories of the licensee (Art. 1 (2)). Where the agreement is a pure know-how licensing agreement exemption may be granted for a period not exceeding ten years counted from the date when the licensed product was put in the market by one of the licensees (Art. 1 (3), First sentence). Where the agreement is a mixed licensing agreement, these obligations are exempted for as long as the licensed product is protected in the Member State in question by such patents if the duration of such protection exceeds the periods specified in Article 1 (3) (Art. 1 (4)).
[157] The information provided above, in note 156, applies equally to this obligation.

distinguish the licensed product during the term of the agreement"[158]. The licensee is nevertheless authorised to identify himself as the manufacturer of the licensed product[159]. Such an obligation is limited by Article 3 (4), which prevents the application of the exemption on the restrictions as to the customers the licensee may serve by "... using certain types of packaging for the products".

Moreover, the licensor may impose an obligation on the licensee, by virtue of Article 1 (1) (8) "... to limit his production of the licensed product to the quantities he requires in manufacturing his own products and to sell the licensed product only" as part of a replacement part of his own products or in connection with the sale of the licensee's products[160]. Such quantities must be freely determined by the licensee himself.

In relation to the protection of the other licensees, Regulation 240/96 provides exemption to obligations imposed on the licensee in three different aspects. Article 1 (1) (4) exempts an obligation on the licensee not to manufacture or use the licensed product or process, in the territories within the Common Market which is licensed to other licensees[161]. This particular situation received particular support from Recital (11) which affirmed that "[t]he exemption of export bans on the licensor and on the licensee does not prejudice any development in the case law of the Court of Justice in relation to such agreements, ... This is also the case, ... regarding the prohibition on

---

[158]In ***Burroughs/Delplanque***, note 71, *supra*, the Commission ruled that the use of the licensor's trade-mark in the licensed invention is necessary to enable the licensor to control the quality and quantity of the products covered by the agreement.

[159]Where the agreement is a pure patent licensing agreement, these obligations are exempted only for as long as the licensed product is protected by parallel patents in the territories of the licensee (Art. 1 (2)). Where the agreement is a pure know-how agreement, these obligation are exempted during the lifetime of the agreement as long as the know-how remains secret and substantial (Art. 1 (3), Third sentence).

[160]The information provided above, in note 159, applies equally to this obligation.

the licensee from selling the licensed product in territories granted to other licensees (passive competition)".

Article 1 (1) (5) accepts an obligation on the licensee not to pursue activities to put the licensed product on the market licensed to other licensees, "... in particular not to engage in advertising specifically aimed at those territories or to establish any branch or maintain any distribution depot there"[162]. The protection from "active sales", however, faces some difficulties regarding the decision whether advertising is aimed at other licensees' territory or not, in so far as television advertising can be easily caught by consumers in other territories within the Common Market and many newspapers are distributed internationally[163]. It is clear, however, that any other export policy, as having agents or sales man or branch, to commercialise the licensed technology in the territory or other licensees is prohibited.

Under Article 1 (1) (6) an exemption may be granted in relation with an obligation on the licensee "... not to put the licensed product on the market in the territories licensed to other licensees within the common market in response to unsolicited orders". This obligation is exempted "... for a period not exceeding five years ..." from the date the product was first put on the market by one of the licensees, as far as this product is protected by parallel patents. In relation to the protection of "passive sales" "... from other licensees, the incentive must be the possibility of earning for five years more than a competitive profit if the investment in tooling up and developing a market is successful"[164, 165].

---

[161]The information provided above, in note 156, applies equally to this obligation.
[162]*Ibid.*
[163]**Valentine Korah**. Patent Licensing and EEC Competition Law - Regulation 2349/84. Oxford: ESC Publishing Limited (1985), p. 40.
[164]*Ibid.*, p. 42.

The obligations listed in Article 1 (1) also apply when parties choose to use these obligations with a more limited scope than is permitted therein[166]. In addition, where the agreement is a pure know-how licensing agreement, the exemptions listed in Article 1 (1) will apply only if the parties have identified the initial know-how and any subsequent improvements to it, only for as long as the know-how remains secret and substantial[167].

Article 2 (1) (the "white list") lists obligations which normally do not infringe Article 85 (1) of the Treaty, but if they did eventually fall within such prohibitions, because of particular economic or legal circumstances, they would be exempted under Article 2 (2). The list provided by Article 2 (1) is not exhaustive[168] and the obligations will also apply where an agreement contains clauses of that type but with a more limited scope than is permitted by Article 2 (1)[169].

Article 2 (1) (1) exempts an obligation on the licensee not to divulge the know-how communicated by the licensor, even after the licensing agreement has expired, as a means of guaranteeing the continuous secrecy of the know-how[170]. It may be suggested, however, that such an obligation will apply only so long as the know-how in question remains secret[171].

---

[165]Note, in addition, that under Regulation 2349/84 such possibility was withdrawn by Article 3 (10) if the licensee was required, for a period of five years, not to put on the market the licensed product in the territories licensed to other licensees within the Common Market.
[166]Art. 1 (5).
[167]Art. 1 (3), Last sentence.
[168]Recital (18).
[169]Art. 2 (3).
[170]Art. 2 (1) (1). This obligations applies even after the agreement has expired as a means of guaranteeing the secrecy of the know-how.
[171]See ***Kabelmetal/Luchaire***, note 72, *supra*.

Article 2 (1) (2) exempts an obligation on the licensee not to assign or sub-licence the licensed technology[172]. Otherwise, the licensor would be restricted in his right of protecting the confidentiality of his secret information. Article 2 (1) (3) exempts an obligation on the licensee not to exploit the licensed know-how after the expiration of the agreement in so far and as long as the know-how remains secret and the patent right is still in force. Such restriction is seen necessary, as far as it guarantees to the licensor the possibility of granting a licence to another undertaking or to exploit the protected technology himself after the termination of the agreement.

Article 2 (1) (4) exempts an obligation imposed on the licensee to grant to the licensor a non-exclusive licence to exploit the improvements to or new applications of the licensed technology. Although the licensee has the right to assign or licence the improvement over the technology of the licensor, the former may not disclose the know-how communicated by the licensor which gave rise to such improvements. Such obligation will be exempted if the licensor undertakes to grant an exclusive or non-exclusive licence of his own improvements to the licensee.[173]

Article 2 (1) (5) includes an obligation which will be exempted if two conditions are met. The obligation is that the licensee shall observe minimum quality specifications for the licensed product or to procure goods or services either from the licensor himself or from some other undertaking designated by the licensor. The conditions to be met are that this is necessary for a technically satisfactory exploitation of the licensed technology and for ensuring that the product of the licensee conforms to the minimum quality specifications that are applicable to the

---

[172] *Cf.* Paragraph 2.1.1, Sub-paragraph (n), *supra*.
[173] *Ibid.*, Sub-paragraph (f), *supra*.

licensor and other licensees. This obligation is understood as necessary also to allow the licensor to carry out related checks with the production and use of the licensed technology.[174]

Article 2 (1) (6) exempts obligations on the licensee to inform the licensor of misappropriation of the know-how or of infringements of the licensed patent or to take or to assist the licensor in taking legal actions against such misappropriation or infringement.

Article 2 (1) (7) permits an obligation on the licensee to continue paying royalties until the end of the agreement even if the know-how becomes publicly available other than by action of the licensor, allowing also an obligation on the licensee to continue paying royalties after the expiration of the agreement, in order to facilitate payments.[175]

Article 2 (1) (8) establishes that restriction on the licensee exploiting the licensed technology to one or more technical fields of application covered by the licensed technology or one or more product markets shall be exempted.[176]

Article 2 (1) (9) exempts an obligation on the licensee to pay a minimum royalty or to produce a minimum quantity of the licensed product or to carry out a minimum number of operations to exploit the licensed technology. In this case, the licensor may reduce the risk relating to the investment in the creative process at the same time that the licensee shall participate of this risk although the latter has not contributed to the development of the technology.[177]

---

[174] *Ibid.*, Sub-paragraph (b), *supra*.
[175] *Ibid.*, Sub-paragraph (g), *supra*. See, also, Recital (21).
[176] *Ibid.*, Sub-paragraph (c).
[177] *Ibid.*, Sub-paragraph (g).

Article 2 (1) (10) exempts an obligation imposed on the licensor to grant to the licensee more favourable terms than the licensor may grant to another undertaking after the agreement is entered into.[178]

Article 2 (1) (11) exempts an obligation on the licensee to indicate the patentee's name or that of the licensed product when marketing it. Article 2 (1) (12) exempts an obligation on the licensee not to use the licensor's technology to construct facilities to third parties. This exemption does not include a limitation to the right of the licensee to increase the capacity of his own facilities or to set up additional facilities for his own use. Article 2 (1) (13) exempts an obligation on the licensee to supply only a limited quantity of the licensed product to a particular customer, as a means of guaranteeing that the customer has a second source of supply inside the licensed territory. This provision applies equally when the customer is the licensee[179]. The licensor may also impose an obligation on the licensee to use his best endeavours to manufacture and market the licensed product[180].

Article 2 (1) also lists the following reservations made by the licensor that is exempted by Regulation 240/96: (a) a reservation of the right to exercise his rights to oppose the exploitation of the technology by the licensee outside the licensed territory[181]; (b) a reservation of the right to terminate the agreement if the licensee contests the secret or substantial nature of the licensed know-how or challenges the validity of the licensed patent[182]; (c) a reservation of the right to terminate the

---

[178] *Ibid.*, Sub-paragraph (m).
[179] *Ibid.*, Sub-paragraph (i).
[180] Art. 2 (1) (17).
[181] Art. 2 (1) (14).
[182] Art. 2 (1) (15). *Cf.* Paragraph 2.1.1. Sub-paragraph

agreement if the licensee claims that the patent is no longer necessary[183]; and (d) a reservation of the right to terminate the exclusivity of a licence and to stop licensing improvements to him when the licensee enters into competition within the Common Market with the licensor or with undertakings connected with him. The licensor may also request the licensee to prove that he is not using the licensed technology for purposes beyond those established by the licensing agreement[184].

Article 3 (the "black list") lists the obligations which are condemned by Regulation 240/96 and, hence, prevents the application of the exempting provisions of the Regulation.[185] The obligations prohibited by Article 3 work mainly as a limitation of the restrictions permitted by Articles 1 and 2.

Article 3 (1) prohibits an obligation on the licensee or the licensor relating to the determination of prices, components of prices or discounts for the licensed products[186]. Article 3 (2) prohibits one party imposing on the other a restriction on competing with the former, or with other undertakings connected with the other party within the Common Market, in respect of research and development, manufacture, use or sales, other than as provided by Articles 2 (1) (17) and (18)[187]. Nevertheless, an obligation which is imposed on the other party to use its best endeavours to exploit the licensed products are outside the scope of Article 3 (2).

Article 3 (3) covers two situations which shall be prohibited. The first is when "one or both of the parties are required without any objectively justified reason" to

---

[183]Art. 2 (1) (16).
[184]Art. 2 (1) (18). (*Cf.* Paragraph 2.1.1. Sub-paragraph (e).
[185]Recital (19) affirms, however, that "[s]uch restrictions may be declared exempted only by an individual decision, taking into account the market position of the undertakings concerned and the degree of concentration on the relevant market".
[186]*Cf.* Paragraph 2.1.1. Sub-paragraph (j).
[187]*Ibid.*, Sub-paragraph (e).

refuse to supply users or resellers in the same territory as the licensed one, who would market such products in other territories within the Common Market[188]. Such a provision is understood as preventing competition and working as a type of export ban. The second type of restriction provided by Article 3 (3) is when one or both of the parties are required, without justified reason,

> to make it difficult for users or resellers to obtain the products from other resellers within the common market, and in particular to exercise intellectual property rights or take measures so as to prevent users or resellers from obtaining outside, or from putting on the market in the licensed territory products which have been lawfully put on the market within the common market by the licensor or with his consent.[189]

This second prohibition is possible basically by the exercise of intellectual or commercial property rights. Other measures relating to this obligation may include restrictions on other licensees or their customers. Furthermore, both situations are condemned also if one or both of the parties do so "as a result of a concerted practice between them".

Article 3 (4) prohibits parties which are already competing manufacturers before the licensing agreement and within the same technical field and within the same product, to impose restrictions on the other party as to the customers he may serve. This applies particularly to prohibitions such as supplying certain classes of user, employing certain methods of distribution, or aiming at sharing customers by using certain types of packaging for the products. This is without prejudice to Articles 1 (1) (7) and 2 (1) (13).

---

[188] Art. 3 (3) (a).
[189] Art. 3 (3) (b).

Article 3 (5) prohibits a restriction on either parties to the quantity of the licensed products one party may manufacture or sell or the number of operations exploiting the licensed technology he may carry out. This is without prejudice to Articles 1 (8) and 2 (1) (13).

Article 3 (6) prohibits an obligation on the licensee to assign to the licensor the whole or part of improvements or new applications of the licensed technology[190]. Finally, Article 3 (7) prohibits an obligation imposed on the licensee to extend the duration of the agreement of any new improvements, for a period of over those determined by Article 1 (2), (3) and (4).

A licensing agreement which does not fall within Regulation 240/96 may apply for an individual exemption under Regulation 17. Nevertheless, to accelerate the process of granting exemptions for agreements which do not qualify for block exemption under Regulation 240/96, Article 4 provides an "opposition procedure" with the aim of facilitating the whole process.[191] Then, agreements which do not qualify for block exemptions may be notified[192] to the Commission[193]. The automatic

---

[190] *Cf.* Paragraph 2.1.1. Sub-paragraph (f).

[191] Although Recital (25) of Regulation 2349/84 argued in favour of the "opposition procedure", by affirming that such a procedure is important to "allow the Commission to ensure effective supervision as well as simplifying the administrative control of the agreement", this procedure has not shown effective practicability. See, generally, **Valentine Korah**, note 163, *supra*, Chapter 7, and **Vivien Rose**, note 14, *supra*, p. 571. See, also, **Commission of the European Communities**, Twentieth Report on Competition Policy, Brussels (1991), p. 46, where the Commission enunciates that in 1990 no notification requesting opposition procedure provide by Regulations 2349/84 and 556/89 was received. See, likewise, **Commission of the European Communities**, Twenty First Report on Competition Policy, Brussels & Luxembourg (1992), pp. 134-135, where the Commission assumes that in 1991 it received eight applications for the opposition procedure, under both Regulations 2349/84 and 556/89, and none of them could apply for such procedure.

[192] Notification shall be done under Regulation N. 3385/94 (OJ 1994 L377/28).

[193] All information acquired by the Commission in relation with "opposition procedures" shall be used only for the purpose of Regulation 240/96 and may not be disclosed by the Commission, by the authorities of the Member States, their officials and other servants. Only information of general character or surveys which do not contain information relating to particular undertakings or association of undertakings, may be published by the Commission or Member States (Art. 9).

exemption will be obtained if, during a period of four months[194], the Commission does not oppose exemption. The Commission, though not obliged to oppose exemption, must do so if it receives a request from a Member State, within two months from the transmission to the latter of the notification[195].[196]

The opposition procedure may be withdrawn at any time by the Commission. However, if the opposition was raised by request of a Member State, and the Member State in question maintains the opposition, it may be withdrawn only after consultation of the Advisory Committee on Restrictive Practices and Dominant Position.[197]

Articles 4 (7) and (8) establish from which date the exemption shall apply in the case of the agreement which has fulfilled all the conditions, and in the case where the agreement was amended in order to fulfil such conditions. In the first case the exemption shall apply from the date of notification and, in the second, from the date that the amendments took effect.

Article 4 (9) provides that if the Commission's opposition is not withdrawn, the effects of such notifications will be governed by Regulation 17. Oddly enough, because the Commission has the right to withdraw the opposition at any time, there is not a clear line determining when such procedure shall begin.

---

[194]Counted from the date on which notification takes effect (Art. 4 (4)).
[195]Art. 4 (5).
[196]The opposition procedure shall apply, particularly, where the "the licensee is obliged at the time the agreement is entered into to accept quality specifications or further licences or to procure goods or services which are not necessary for a technically satisfactory exploitation of the licensed technology" (Art. 4 (2) (a)) and where "the licensee is prohibited from contesting the secrecy or the substantiality of the licensed know-how or from challenging the validity of patents licensed within the common market belonging to the licensor or undertakings connected with him" (Art. 4 (2) (b)).
[197]Art. 4 (6).

Article 5 establishes that Regulation 240/96 does not apply in relation to five specific matters. The reason why these five types of agreements were included in Article 5 is justified by Recital (8) on grounds that "[s]uch agreements pose different problems which cannot at present be dealt with in a single regulation". The first case which is excluded is when the agreement is between members of a patent or know-how pool which relates to the pooled technologies[198]. A patent pool cannot always be separated from the understanding of a joint venture what could lead the Commission to assess licensing agreements taking into consideration different Community requirements. Regulation 240/96 will nevertheless apply to licensing agreements provided the parties are not subject to any territorial constraint within the Common Market with regard to the manufacture, use or putting on the market of the licensed product or to the use of the licensed pooled technologies[199].

The second situation is when a licensing agreement is settled between competitors who hold interest in a joint venture or between one of these competitors and the joint venture[200]. This provision applies only if the agreement is directly related with the activities of the joint venture in question and the members of the joint venture are actual competitors. Notice, additionally, that if the product, related to the agreement, represents, "in case of a licence limited production, not more than 20%, and in case of a licence covering production and distribution, not more than 10%, of the market for the licensed products and all interchangeable or substitutable goods and services", Regulation 240/96 applies to such agreements[201]. Further, Regulation 240/96 continues to apply where for two consecutive financial years the market shares

---

[198] Art. 5 (1) (1).
[199] Art. 5 (2) (2).

are not exceeded by more than one-tenth. When the limit is exceeded, Regulation 240/96 continues to apply "... for a period of six months from the end of the year in which the limit is exceeded"[202]. The Commission's approach in this regard, which was included as part of Regulations 2349/84 and 556/89 by amending Regulation N. 151/93[203], seems to represent a cornerstone economic point of view concerning the effects of the product in question in the competition within the Common Market and part of the introduction of the "market share" concept included in the assessment of exemptions by Regulation 240/96, which will be analysed further below.

The third aspect which does not benefit from Regulation 240/96 is related to agreements between one party which grants a licence to another party and that other party, although through "separate agreements or through connected undertakings", grants to the first party a patent, trade-mark or know-how licence[204]. In this case parties have to be competitors in relation with the products covered by the licensing agreement. Moreover, Article 5 (2) (2) includes the view that Regulation 240/96 shall apply to reciprocal licences if no territorial restriction is provided by the agreement in question "within the common market with regard to the manufacture, use or putting on the market of the licensed product or to the use of the licensed or pooled technologies".

The fourth aspect which will not benefit from the application of block exemption under Regulation 240/96 is licensing agreements containing provisions

---

[200]Art. 5 (1) (2).
[201]Art. 5 (2) (1).
[202]Art. 5 (3).
[203]Note 2, *supra*.
[204]Art. 5 (1) (3).

relating to IPRs other than patents which are not ancillary[205]. In addition, agreements entered into solely for the purpose of sale will not benefit from the application of Regulation 240/96[206]. It is also worth mentioning that, following Court decisions and other criticisms towards the non-applicability of Regulation 2349/84 to licensing agreements in respect of plant breeders' rights, Regulation 240/96 has not excluded licensing agreement on plant breeders' rights from the application of the block exemption rules[207].

Article 6 determines that Regulation 240/96 shall apply also to: agreements where the licensor is not the holder of the know-how or the patentee, but is authorised by the holder of the patent to grant a licence[208]; assignments of know-how, patents or both where the risk associated with exploitation remains with the assignor[209]; and licensing agreements in which the rights or obligations of the licensor or the licensee are assumed by undertakings connected with them[210].

In Article 7, Regulation 240/96 establishes the "market share" concept. It must be understood as a reaffirmation of the Commission's power to withdraw the benefit of Regulation 240/96 where it finds in a particular case that an agreement exempted by Regulation 240/96 has certain effects that are incompatible with the conditions laid down by Article 85 (3) of the Treaty. Article 7, for this purpose, provides in particular the following situation:

---

[205] Art. 5 (1) (4).
[206] Art. 5 (1) (5). Recital (8) supports such exclusion by affirming that "... this Regulation should apply only where the licensee himself manufactures the licensed product or has them manufactured for his account, or were the licensed product is a service, provides the service himself or has the service provided for his account, irrespective of whether or not the licensee is also entitled to use confidential information provided by the licensor for the promotion and sale of the licensed product".
[207] *Cf.* note 135, *supra*.
[208] Art. 6 (1).
[209] Art. 6 (2).

> [where] the effect of the agreement is to prevent the licensed products from being exposed to effective competition in the licensed territory from identical goods or services or from goods or services considered by users as interchangeable or substitutable in view of their characteristics, price and intended use, which may "in particular occur where the licensee's market share exceeds 40%",[211]

A broader approach to technology transfer and dissemination was included in the first draft of Regulation 240/96[212] and suffered several criticisms from businessmen and scholars[213]. The draft Regulation proposed, in Article 1 (5), that the exempted obligation on the licensor not to licence other undertakings to exploit the licensed technology in the licensed territory[214] would apply only provided:

> - that the products manufactured by the licensee which are capable of being improved or replaced by the contract products and other goods manufactured by him which are considered by users to be equivalent in view of their characteristics, price and intended use account for more than 40% of the entire market in those products in the common market or a substantial part of it, and
> - that the licensee is not operating on an oligopolistic market; for the purposes of this regulation the market is to be considered as an oligopolistic one if on the relevant product and geographic market three undertakings or less hold together a market share of more than 50%, or if five undertakings or less hold together a market share of more than two thirds and provided that the licensee is one of the undertakings which make up this group of companies and that it holds a market of more than 10%.

This approach seems to be hardly acceptable to business in so far as block exemptions would be necessarily more difficult to obtain in a continuous basis. The

---

[210]Art. 6 (3).
[211]Art. 7 (1). Emphasis added. See also, Recital (26).
[212]*Cf.* note 144, *supra*.
[213]See, *e.g.*, **Robin Whaite**, The Draft Technology Transfer Block Exemption, [1994] 7 *EIPR* 259-262, and **Valentine Korah**, The Preliminary Draft of a New EC Group Exemption for Technology Licensing, [1994] 7 *EIPR* 263-286.
[214]Art. 1 (1) (1).

licensee would have to bear with constant tests on its market share, in so far as once the technology is widely disseminated and known by the market and the consumers, the "oligopolistic position" would be reached easily. In addition to that, it seems that such a market share concept would create more problems than solve them, because of the difficulty to provide an accurate technical economic analysis of the position of the licensees and licensors in a substantial part of the entire Common Market[215]. The Commission appears to have taken into account these criticisms and the possible effects of a stricter "market share" concept and excluded this provision from Regulation 240/96.

Article 7 (2) finally affirms that the Commission may withdraw exemptions already granted when the licensee refuses to meet unsolicited orders from users or resellers in the territory of other licensees, without prejudice to Article 1 (1) (6). Under Article 7 (3), either parties of a licensing agreements are also prohibited to refuse to meet orders from users or resellers in their respective territories who would market the products in other territories of the Common Market, or to make it difficult for users or resellers to obtain the products from other resellers within the Common Market, and in particular when they exercise IPRs or take measures so as to prevent users or resellers from obtaining the products outside the licensed territory, aiming at restricting the free flow of goods within the Community.

Article 8 affirms that the following shall be deemed to be patents: patent applications; utility models; applications for registration or utility models; topographies of semiconductor products; *certificats d'utilité* and *certificats d'addition* under French law; supplementary protection certificates for medicinal

products[216] or other products for which such supplementary protection certificates may be obtained; and plant breeders'rights[217].

Article 10 provides an exhaustive list of definitions for terms used in Regulation 240/96. Article 11 revokes Regulation 556/89 from 1 April 1996 and gives effect to Regulation 2349/84 until 31 March 1996. Article 12 affirms that the Commission shall take regular assessments of the application of the provisions of Regulation 240/96, particularly in relation with the opposition procedure laid down by Article 4, and determines that the Commission shall draw up a report on the operation of Regulation 240/96 before the end of the fourth year following the entry into force of the Regulation and, on that basis, decide whether or not an adaptation of the Regulation is necessary. Article 13 determines that Regulation 240/96 enters into force on 1 April 1996 and shall last until 31 March 2006.

2.2. Patent rights and Article 86

Article 86 of the Treaty is, together with Article 85, the effective implementation of the general objective established by Article 3 (g), aiming to ensure a system of competition within the Common Market which will not be distorted. The purpose of Article 86 is to control the abusive exercise of an undertaking (or of more than one undertaking) which holds a dominant position within the Common Market. Article 86, *caput*, determines:

---

[215]See **Valentine Korah** and **Robin Whaite**, note 213, *supra*, for this opinion.
[216]For further discussion relating to supplementary protection certificates for medicinal products, see Chapter 4, Section 3, Sub-section 3.3, Paragraph 3.3.1, *infra*.
[217]*Cf.* note 135, *supra*.

> Any abuse of one or more undertakings of a dominant position within the common market or in substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.

Further, Article 86 lists examples of practices which shall constitute an abuse of a dominant position such as the imposition of unfair prices or unfair trading conditions[218], the limitation of production, market or technical development to the prejudice of consumers[219], the imposition of different conditions upon equivalent transactions placing the other party with competitive disadvantages[220], and the imposition to other parties of conditions or supplementary obligations which have no connection with the subject of the contract[221].

Article 86 thus involves three essential elements. For the application of this Article there must be a dominant position by an undertaking, or a group of undertakings, in the Common Market or in a substantial part of it. The exercise of this dominant position has to constitute an abuse and its consequence shall be the effect on trade between Member States. What should be made clear, however, is that Article 86 does not prohibit the dominant position, but only the abusive exercise of such position.

Dominance may exist in two ways:

> Dominance can exist both in the supply and in the purchase of goods or services. In order to determine whether an undertaking occupies a dominant position it is necessary first to identify the relevant market - ie the relevant product or service market and the relevant geographic market. Application of Article 86 requires dominance within the common market "or a substantial part of it". A "substantial part" of the

---

[218]EC Treaty Art. 86 (a).
[219]*Ibid.*, Art. 86 (b).
[220]*Ibid.*, Art. 86 (c).
[221]*Ibid.*, Art. 86 (d).

> common market may be the territory of a single member state or even part of a member state. Having identified the relevant markets, it must then be shown that an undertaking (or group of undertakings) is dominant in those markets. A very high market share - more than 85 per cent - is determinative of itself of a dominant position; a market share of 50 per cent constitutes a dominant position except in exceptional circumstances. Whether dominance can exist with a lower market share depends upon the restrictive market shares of the undertaking and its competitors, their respective technical, financial or other resources (such as intellectual property rights) and the undertaking's conduct in the market.[222]

To define the existence of the dominant position in the Common Market or in a substantial part of it, a definition of the market in question must be considered in the first place - the relevant product market - followed by the analysis of the position of the undertaking with a high share of activity in such market, and the possibility of actual or potential competitors to threaten the position of the dominant undertaking.[223]

The second element for the application of Article 86 is whether or not the undertaking which holds a dominant position in the Common Market, or in a substantial part of it, acts in such a way that constitutes an abuse of its position. Article 86 lists examples of conduct of undertakings which may be considered an abusive practice.

The effect on trade between Member States shall be understood in the same way as the wording of Article 85. The activity of an undertaking, if not affecting trade

---

[222]**David A.O. Edward & Robert C. Lane**, note 3, *supra*, pp. 109-110, para. 234. The Court accepted a very high market share with the power to impede effective competition as an evidence of a dominant position. See, *e.g.*, Case 27/76 ***United Brands* v. *Commission*** [1978] ECR 207, [1978] 1 CMLR 429 and Case 85/76 ***Hoffmann-La Roche* v. *Commission*** [1979] ECR 461, [1979] 3 CMLR 211.

[223]**Vivien Rose**, note 14, *supra*, p. 593.

between at least two Member States, but providing for the possibility of doing so, is already condemned by Article 86.

The prohibition established by this Article may be applied to the activities of private and public undertakings. It is noteworthy that a "... dominant position may be acquired over time by economic performance by private undertakings or it may be conferred by statute upon a 'public undertaking' or upon undertakings to which Member States grant special or exclusive rights"[224].

The main difference between Articles 85 and 86 of the Treaty, though both Articles' goal is to ensure the principle established by Article 3 (g) of the Treaty, is that under Article 85 there is a possibility of exemption of an agreement. No such possibility is available for an undertaking which falls within the prohibition established by Article 86. In ***Tetra Pak* v. *Commission***[225] the Court of First Instance drew principles concerning the relationship between both provisions and emphasised the distinctions between them.

When one considers that patent rights grant a monopoly through national rules to the patentee, it is important to bear in mind that this is not enough by itself to establish a dominant position, nor may the exercise of such right constitute an abusive exercise of a dominant position. The Court, for the first time, analysed the application of Article 86 concerning the exercise of patent rights in ***Parke, Davis & Co.* v. *Centrafarm***[226] In this case, the rights of a holder of two Netherlands patents for biological and chemical manufacture of an antibiotic, Parke, Davis & Co., had been infringed by the marketing of such product in the Dutch market by Probel, a Belgian

---

[224]*Ibid.*, p. 404.
[225]Case T-51/89, note 8, *supra*.

company, and by Interpharm and Centrafarm, both Dutch companies. The importation of the product from various countries of Europe was not done with the consent of the patentee, nor with the permission of the licensee in the Dutch market. A preliminary ruling, under Article 177 of the Treaty, requested the Court to decide how far a high price charged for a product in the Dutch market, directly or indirectly, constitutes a breach of the rules of the Treaty, if a parallel importation of the product, done by Centrafarm from Italy where such protection was not available, could supply the market with lower prices for the same product.

Advocate-General Roemer, analysing the questions raised by the Dutch Court, emphasised that the existence of a patent right, by itself, is not enough to fulfil the requirement of Article 86 since it is not, as such, a proof of a dominant position and, further, stated that "... not all the actions of the person who enjoys a monopoly are illegal, but only those which have been carried out with the help of a dominant position"[227]. In this case, Roemer understood that the difference of price was essentially based on the very heavy costs involved on the research of such product. He considered that to pay such costs and to be recompensed for the creative effort, by profiting on the marketing of the patented product, falls within the specific subject-matter of a patent. Furthermore, he understood that in a country where no protection is available, an undertaking may, based on published specifications, exploit an invention without incurring further costs, being able, hence, to offer the product in another Member State at lower prices.

The Court, following Advocate-General Roemer, held:

---

[226]Case 24/67, note 13, *supra*.
[227]*Ibid.*, [1968] ECR, p. 79.

> ..., since the existence of patent rights is at present a matter solely of national law, the use made of them can only come within the ambit of Community law where such use contributes to a dominant position, the abuse of which may affect trade between Member States.
>
> Although the sale price of the protected product may be regarded as a factor to be taken into account in determining the possible existence of an abuse, a higher price for the patented product as compared with the unpatented product does not necessarily constitute an abuse.[228]

To establish the position of a patent holder as a dominant one, all the requirements of Article 86 must be taken into account. A dominant position is, nevertheless, an economic concept which is unlikely to be analysed under an abstract view. A more technical assessment is necessary to find out whether or not an undertaking is in a dominant position. In a later case, ***Hoffman-La Roche* v. *Commission***[229], the Court, according with the Commission's view, said that a relevant consideration to make the position of dominance clearer was that the undertaking in question possessed technological advantage amongst other competitors. In this case, Hoffman-La Roche clearly had financial and technological resources to develop products or technical services with an advantage over its competitors.[230]

Other situations concerning the exercise of intellectual property rights may be understood as an infringement of Article 86. In another case, ***Eurofix-Bauco* v. *Hilti***[231], the Commission held that it was an abuse of a dominant position to demand

---

[228] *Ibid.*, at p. 72.

[229] Case 85/76, note 222, *supra*.

[230] See, for a more recent decision, ***Tetra Pak* v. *Commission***, note 8, *supra*, where the Court of First Instance held that with the acquisition of another company, obtaining the exclusivity of a patent licence for a sterilisation process for milk packing, Tetra Pak would strengthen its dominant position in the market.

[231] OJ 1988 L65/19, [1989] 4 CMLR 677.

high royalty payments and, for this reason, to delay the time when a licence of right would be available.

In relation to patent rights it is easier to envisage an evidence of a dominant position. However, it is important to emphasise that the mere existence of such right cannot be mixed up with the concept of dominance. Moreover, the prohibition established by Article 86 applies only if the patent right establishes a dominant position for its holder and the patent holder exercises his rights in a way which is considered abusive, thus affecting trade between Member States and acting against the principles established by the Treaty.

From the many cases decided by the Court, it seems that the holder of a patent right, when in a dominant position, is required to grant licences to anyone capable of paying a reasonable royalty[232]. The patentee, in a dominant position, is also required to supply the protected product to third parties without imposing unfair conditions. Moreover, it is clear that if the patentee in a dominant position exercises his rights in ways which may affect trade between Member States, as described by paragraphs (a) to (d) of Article 86, he will be abusing his position and thus acting against the prohibition of Article 86.

CONCLUSION

There are several considerations provided by the present Chapter which are of relevance to the MERCOSUL. The first, and most obvious one, is that the control of

[232]In a more recent case related with the exercise of copyright (Joined Cases C-242 P and C-242/91 P ***RTE and ITP*** **v.** ***Commission*** [1995] ECR-I 743, known as the "Magill Case"), the Court held that the refusal to grant a licence for television programme listings for weekly publication, against the payment of reasonable royalties, may breach Article 86 of the Treaty. Although this case is related with copyright licensing, such judgment seems to confirm that undertakings in a position of

the exercise of patent rights within an integrated area is of paramount complexity and importance. What can be learned from the experience in the EU is that a well defined supranational institutional framework has played a determinant role in the setting up of rules and principles for the establishment and functioning of the integrated area. As has been noted in Chapter 1, Section 2, *supra*, the institutional framework established by the Ouro Preto Protocol does not provide for organs with supranational powers to decide upon disputes, which would eventually harmonise the juridical interpretation of the common legal measures of the MERCOSUL, and enforce common regulations.

Additionally, it is possible to oversee a clear inter-action between the application of the free movement of goods principle with the establishment of a common area where a healthy competitive market shall prevail. This is emphasised by the conflict between the laws of the MERCOSUL and those of the States Parties. Neither the Treaty of Asuncion nor the Ouro Preto Protocol provide a more detailed legal framework on the application of the principle of free movement of goods and the understanding on common rules for competition. This may be viewed as both an advantage and as a problem. Firstly, it is advantageous because it leaves much room for further definition of such complex issues during the negotiations that have been carried out to implement the concepts of the Treaty of Asuncion. Secondly, it poses problems for the establishment and functioning of the integrated area in so far as there is no constitutional basis to guide the implementation of the common legal measures that will be applied for in practical situations. These two characteristics are to be

---

dominance must grant intellectual property licences to all other undertakings which are willing to pay reasonable royalties.

taken into account when drawing up common measures to regulate commercial practices within the common territory of the MERCOSUL.

The main goal of the MERCOSUL, as that of the EC, is to create an integrated economic and commercial system similar to national systems. This raises questions related to the implementation of the common rules to be applied in the territory of the MERCOSUL as well as the application of national rules related to anti-competitive practices. It is initially necessary to note that the dimension of the application of the free movement of goods principle between two or more countries makes the legal analysis of the matter even more complex. This Chapter has shown several circumstances that are of concern for integrating projects. In this regard, a possible doubt is how a temporary monopoly sponsored by national law (as the case of patents) will be dealt with in the context of the integrated area of the MERCOSUL. Patented products, know-how and technology are allowed to circulate without any barriers in the territory of the MERCOSUL and, as has been seen throughout the present analysis, the exercise of patent rights may, in some circumstances, impose unlawful barriers on the free flow of patented goods. How will lawful and unlawful practices be defined in the context of the MERCOSUL? Of course common regulatory mechanisms are necessary for defining and limiting commercial practices of patent holders and licensees and an effective harmonisation process ought to take place. The legislative outcome of the MERCOSUL process has to be constructed in detail to equip the integrated area with a common set of norms which would be valid throughout its territory, offering business legal certainty, as a result of clearer rules, and limits for commercial practices. These rules must foresee situations which run

against competition law and also situations which are to be decided in a case-by-case basis. Secondly, it may be possible to derive from the European experience that anti-competitive practices directly affect trade between members of integrating projects which, as a consequence, restrict the free circulation of goods in that particular common area. This relationship between free movement of goods and an undistorted competitive market becomes even more complex when no guidance is provided by the constitutional principles of the Treaty of Asuncion. It is more difficult to envisage a practical solution to this problem if, in the case of disputes, no institutional mechanism is provided for harmonising the understanding of national courts.

It is also possible to draw a parallel with the situation in the EC. As emphasised by both the EC Treaty and the Treaty of Asuncion, measures having equivalent effect to quantitative restrictions is prohibited and that is the particular situation of IPRs. At this stage of discussion, a balance between national and common interest, as well as between private and public (liberalisation of trade) interest, has to be established. National courts will play a determinant part in this direction but will have no guidelines to act in harmony with national courts of other States Parties of the MERCOSUL. The conflict between the existence of national patent rights and the inherent exercise of these rights within an integrated territory has to be limited to fit into the interest of free trade and an undistorted competitive environment.

I am not suggesting that the experience of the European Community, as described in the present Chapter, must be used as a definite model for the integration project of the MERCOSUL. This is so for many reasons, not least of which is because the characteristics of the States Parties of the MERCOSUL and its undertakings,

differ in substance from those of the European Community. I propose to give the details of the European experience as a means to facilitate the preparedness of the integration process of the MERCOSUL to suggest possible future problems and scenarios. However, the present analysis intends to establish only general conclusions of more immediate utility for the MERCOSUL. The analysis of these measures in the MERCOSUL will be further discussed in Chapter 6, below.

At this point, I should like to suggest that there are strong reasons to lead me to think that the institutional framework established by the EC Treaty is relatively exhaustive and provides more solutions for the harmonisation of national legal and juridical concepts than the institutional framework provided by the Treaty of Asuncion and the Ouro Preto Protocol. Within the EC, the Commission and the Court have played crucial roles for the setting up and operation of the integrated area.

In the case of harmonisation or unification of national laws there are already legislative functions assigned to different organs of the MERCOSUL. These organs have, since the signature of the Treaty of Asuncion, worked in harmony and provided the process itself with a variety of necessary common regulations. The legislative functions performed by the MERCOSUL are indeed working, though there is no democratic representative body. Nevertheless, in the case of patent rights, the legislative outcome has not been that effective, lacking precise definitions on substantive patent law, competition law and regulatory measures on the free movement of goods. These regulations are extremely necessary to aid national administrative and juridical organs to decide upon particular circumstances while considering in practice the integration process of the MERCOSUL. The harmonisation of national laws regulating patent rights must also consider the needs

and the stage of technological development of the industries of the region, as well as the necessary strategies to encourage foreign investment in the MERCOSUL. Therefore, the setting up of common regulations in the field of patent rights must be in conformity with a common science and technology policy for the region, as well as a joint industrial policy, as a means of determining the boundaries of the application of the common rules for the MERCOSUL.

Following the discussion which took place in the present Chapter, it is worthy noting that there are two other issues, related to attempts to establish a harmonised patent system in a regional basis, which are relevant to the present research. The first is the setting up of the European Patent Convention (EPC) which has been applied since the mid-1970s. The EPC has proved to be an effective system, although its application is not directly related with a harmonised approach towards patent protection in a Common Market. The other, the Community Patent Convention (CPC) which attempted to create a very detail system of jurisdiction inter-related with the EPC patent granting system, has not come in force so far.

This complementary discussion takes place in Chapter 4, below, aiming to provide the negotiating process of the MERCOSUL with a detailed view of a possible solution towards the harmonisation of substantive patent laws, and the creation of a system which would unify administrative and juridical patent decisions, possibly through the mechanism of inter-state conventions.

CHAPTER 4
UNIFICATION OF NATIONAL LAWS: THE COMMUNITY PATENT CONVENTION

INTRODUCTION

Chapter 3, above, provided information about several legislative, administrative and juridical actions taken by the EC and concludes with some general guidelines for the integration project of the MERCOSUL. As described in Chapter 3, the EC has carried out, in this researcher's opinion, a rather efficient legislative and juridical way to harmonise regulations on patent issues in the Common Market, as a means of defining the limits of patentees' practices ensuring that the integration process as a whole would be established and operate successfully. Chapter 3 emphasised that the Commission and the Council have played a crucial role in setting up common rules for the European integration process.

The EC has, in addition, attempted to unify substantive patent law and the economic effects of the exercise of patents within the Common Market, through the mechanism of inter-State Convention. This attempt has suffered many draw backs and does not seem feasible within the European context, as will be further discussed in this Chapter. As the practice described in Chapter 3 has been relatively successful for the setting up of the integrated system, it is also necessary to describe the other side of the story which is highlighted by the difficulties of unifying national patent principles through a single multilateral instrument. This experience is also of relevance for the integration process of the MERCOSUL in so far as the latter is considering the harmonisation of IPRs through multilateral mechanisms and giving little, if any, emphasis to common regulatory measures to regulate the exercise of patent rights.

This Chapter considers the harmonisation process of patent law in the European Community. The establishment of a common system of jurisdiction, enforcement and standards of substantive law for patent protection is seen as a cornerstone not only of the issues on the establishment of a Common Market, but further as a key point of the functioning of the integrated system that is now the European Community. The EC Treaty expressly lists the "approximation of laws" as one of the main objectives to be reached by the Member States "... to the extent required for the proper functioning of the common market"[1].

In the case of patent protection, the harmonisation process itself is drawn by the EC Treaty, *inter alia*, for the purposes of ensuring the application of the principle of free circulation of goods and the establishment of a system in which competition would not be distorted[2], making national laws similar in order to have uniform protection and enforcement of inventions at national and Community levels. Although some of the problems arising from the exercise of patent rights within the Community have been harmonised by case law[3], the problem was not fully exhausted by the various questions brought before the European Court of Justice. The Court itself has pointed out that the problems of intellectual property rights within the Community are essentially based on the

---

[1]EC Treaty, Art. 3 (h). The term "approximation", as used in this paragraph, is employed by the Treaty with a variety of terms. It is used, for example, "approximation" also in Articles 27, 45, 100 and 117; "co-ordination" in Articles 54, 56, 57 and 70; "harmonisation" in Articles 99, 112 and 117; "making equivalent" in Article 54; or "the adoption of common rules" in Article 75. It does not seem, however, that there is a great difference among all these terms employed by the EC Treaty. Some authors nevertheless understand that the term "approximation" represents "... a more intensive process of integration than harmonisation" (**D. Lasok & J.W. Bridge**, Law and Institutions of the European Communities. London & Edinburgh: Butterworths & Co. (Publishers) Ltd. (1991), 5th ed., p. 534). Despite that, these terms, when used in this Chapter, should be understood as equivalents.

[2]See, generally, Chapter 3, *supra*, for a more detailed analysis of the conflicts between patent rights and the objectives established by the EC Treaty.

[3]*Ibid.*

differences among national systems of law and suggests that a solution would come up when those systems were unified.[4]

Article 100 of the Treaty sets out the legal instruments which will be used by the Community in order to remove the differences among national laws which "... directly affect the establishment or functioning of the common market". For this purpose, the Council is empowered to issue directives or make regulations for the approximation of the national provisions of the Member States[5]. It is argued that, by its nature, directives are a more appropriate instrument for the harmonisation process established by Article 100, in so far as it leaves to the national authorities the choice of form and method of implementation of Community rules. They do not intend to replace national laws. On the other hand, because of their general application, and the fact that they are binding in their entirety - being directly applicable in all Member States - regulations are not seen as the best instrument for harmonisation purposes, but rather for the purposes of unification of laws.[6]

---

[4]See, *e.g.*, Case 24/67 ***Parke, Davis & Co.* v. *Centrafarm*** [1968] ECR 55, p. 71, and the opinion of the Advocate-General Trabucchi in Joined Cases 15 & 16/74 ***Centrafarm* v. *Sterling Drug*** [1974] ECR-II 1147, p. 1176.

[5]The Council was initially empowered by the EC Treaty to adopt harmonisation measures by unanimity. As a result of the inclusion of Articles 100a and 100b by the Single European Act (Arts. 18 and 19, respectively), the Council was empowered, with some exceptions, to do it by qualified majority. Currently, after the amendments included by the Maastricht Treaty, the Council is required to act unanimously on a proposal of the Commission and after consulting the European Parliament and the Economic and Social Committee. Note that, as a result of the entering into force of the Maastricht Treaty, the Council now may legislate only together with the European Parliament. The latter was given great power of decision and veto against the Council's decisions and legislative initiatives, enhancing its participation in the legislative process of the Community. See, *e.g.*, EC Treaty, Arts. 189 to 191.

[6]See, generally, **A.J. Easson**, EEC Directives for the Harmonisation of Laws: Problems of Validity, Implementation and Legal Effects, [1981] 1 *YEL* 1-44, pp. 2-3, and **Alan Dashwood**, The Harmonisation Process, in **Carol C. Twitchett** (ed.), Harmonisation in the EEC, London: The MacMillan Press Ltd. (1981). A detailed discussion on this matter is outside the scope of this Chapter. For a more specific analysis on the harmonisation of national laws within the EC, see the two references quoted above and, **George Close**, Harmonisation of Laws: Use or Abuse of the Powers under the EEC Treaty?, [1978] 3 *EL Rev.* 461-481; **Julian Curral**, Some Aspects of the Relation Between Articles 30-36 and Article 100 of the EEC Treaty, with a Closer Look at Optional Harmonisation, [1984] 4 *YEL*, 169-206; **Jacques Pelkmans**, The New Approach to Technical

Traditionally, in international law, the most common instrument for the harmonisation is the "inter-State Convention". The EC Treaty itself, in Article 220, contemplates the conclusion of conventions for specific matters. In the case of the harmonisation of patent law, the Council of Europe envisaged, as early as 1949, that the Convention was the best instrument for the unification of the national patent laws of the Member States.[7] Later, in 1959, a working group was established for the creation of a uniform system of patent protection for the EC aimed to prevent patents being used as trade barriers within the Common Market[8]. The working group started to work on the preparation of this Convention in 1961 and drafted a proposal that was published in 1962. Because of political problems related to the adherence of the United Kingdom to the EEC this Convention did not come into force at that time.[9] However, the substantive provisions

---

Harmonization and Standardization, [1987] 25 *Journal of Common Market Studies* 249-269; **T.W. Vogelaar**, The Approximation of the Laws of Member States under the Treaty of Rome, [1975] 12 *CML Rev.* 211-230; and **Daniel Vignes**, The Harmonisation of National Legislation and the EEC, [1990] 15 *EL Rev.* 358-374.

[7] As a first attempt at harmonising patent law in Europe, a "European Convention Relating to the Formalities Required for Patent Applications" was signed in Paris in 1953, which eventually came into force on 1 June 1955 ((1980) 19 *Industrial Property* 21). At that time, the purpose was not to establish a European Patent Office as such, but to "... entrust the existing national examining Patent Offices with the granting of European patents with effect for the combined territories of all participating States. These national Patent Offices would then simply apply their own national provisions" (**M. van Empel**, The Granting of European Patents, Leyden, The Netherlands: A.W. Sijthoff International Publishing Company B.V. (1975), p.11).

[8] This programme provided, more extensively, for the preparation of drafts for the unification of the legislation on patents, trade-marks and designs.

[9] The "Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions", done at Strasbourg on 27 November 1963 ((1964) 3 *Industrial Property* 13) eventually came into force on 1 August 1980, with the ratification or accession of France, Germany, Ireland, Liechtenstein, Luxembourg, Sweden, Switzerland and the United Kingdom ((1981) 20 *Industrial Property*, 25). See, also, for this information, **Gerald Paterson**, The European Patent System: The Law and Practice of the European Patent Convention Oxford: Sweet & Maxwell Ltd. (1992), p. 16, and **Günter Gall**, Legislative and Judicial Power in Europe - How far is Harmonisation of Patent Law and Practice Possible and Desirable? [1988] 5 *EIPR* 138-142, p. 141. For further analysis of this Convention, known as the "Strasbourg Convention", see, *e.g.*, **G. Oudemans**, The Draft European Patent Convention: A Commentary with English and French Texts, London: Stevens and Sons Limited (1963); **Franz Froschmaier**, Some Aspects of the Draft Convention Relating to a European Patent Law, [1963] 12 *International and Comparative Law Quarterly* 886-897; and **W.L. Haardt**, Infringement Procedure According to the Draft Convention Relating to a European Patent Law, [1963-1964] 1 *CML Rev.* 202-209.

of this Convention were later incorporated into other developments of the European patent system.[10]

Then, in December 1968 the French Government stated its position towards the conclusion of an agreement on the setting up of a European patent system. This agreement should provide a centralised system involving non-EEC States known for their industrial and technical capacity, such as the United Kingdom, and the establishment of a unified patent system for the Common Market. At the beginning of 1969 the EEC Council approved a proposal for an inter-governmental conference on this issue, which had its first meeting in May 1969[11]. The main reasons for the establishment of such a system were both political - *i.e.*, the creation of a common patent system for the EEC in order to eliminate distortions of competition which would result on the promotion of the free movement of goods - and practical - *i.e.*, the creation of a centralised system which would rationalise the granting of patents in Europe, avoiding duplication of search and examination of patent applications, bringing the costs of patents down[12].

The results of the process came up in 1973, with the signature of the Convention on the Grant of European Patents (the European Patent Convention)[13], followed by the signature of the Convention for the European Patent for the Common Market (the

---

[10]**Gerald Paterson**, note 9, *supra*, pp. 16-17. Mainly the provisions on patentable subject-matter were very much incorporated by the European Patent Convention, note 13, *infra*.

[11]**M. van Empel**, European Patent Conventions: the First Convention in the Semi-Finals, [1972] 9 *CML Rev.* 456-465, p. 15.

[12]**J.B. van Bethem**, The European Patent System, Today and in the Future, [1984] 7 *EIPR* 182-188, p. 185.

[13]Signed on 5 October 1973 and amended by Decision of the Administrative Council of the European Patent Organisation of 21 December 1978 (OJ EPO 1979, 3) (hereinafter the "EPC"). As printed in **Gerald Paterson**, note 9, *supra*, Appendix 1. For an analysis of the negotiations and draft proposals of the EPC, see, generally, **M. van Empel**, European Patent Conventions, [1972] *9 CML Rev.* 13-34; **M. van Empel**, note 11, *supra*, and; **R. Bowen & A. Parry**, European Patent Convention: The First Convention, [1974] 11 *CML Rev.* 105-113.

Community Patent Convention)[14]. After the signature of the Community Patent Convention in 1975, two conferences took place in Luxembourg on the CPC: (a) in 1985 when a first round of amendments to the Convention was provisionally established[15], and (b) in 1989 when the Agreement Relating to Community Patents was signed[16]. Another Conference, called by the "Protocol on a possible modification of the conditions of entry into force of the Agreement relating to Community patents"[17], took place in Lisbon, on 4 and 5 May 1992. This Conference was empowered to amend, unanimously, the number of States which must have ratified the Agreement in order for it to enter into force[18], without the ratification by Denmark and Ireland, leaving Spain and Portugal with the option of not applying the CPC until 1996. This Conference failed to find a way of bringing the Convention into force without the ratification by, at that time, the twelve Member States of the Community[19].

---

[14]Signed in 1975 and printed in OJ 1976 L17 (hereinafter "CPC 1975"). Also there was the signature of the Patent Cooperation Treaty in 1970, under the auspices of the WIPO. The PCT, although not negotiated in the context of the EPC and CPC, is closely related with both Conventions. For further reference to the PCT, see Chapter 2, Section 1, Sub-section 1.3, *supra*.

[15]**Council of the European Communities**, Texts Established by the Luxembourg Conference on the Community Patent 1985 (1986).

[16]Agreement Relating to Community Patents - Done at Luxembourg on 15 December 1989, printed in OJ 1989 L401 (hereinafter the "Agreement"). Article 1 of the Agreement states that the Community Patent Convention signed in 1975, as amended by the Agreement (hereinafter the "CPC"), the Protocol on the Settlement of Litigation concerning the Infringement and Validity of Community Patents (hereinafter the "Protocol"), the Protocol on Privileges and Immunities of the Common Appeal Court, and the Protocol on the Statute of the Common Appeal Court shall form an integral part of the Agreement.

[17]OJ 1989 L401/51.

[18]*Ibid.*, Art. 1.

[19]See, for more detailed information on the outcome of this Conference, the "Report from the President of the Lisbon Conference on the Community Patent to the EC Council", 7373/92, EN. Although constitutional problems in Ireland and Denmark prevented the Convention from coming into effect, according to the Danish delegation, during this Conference, the procedure for ratification of the Agreement was under way in Denmark and should be completed shortly and, the Irish delegation informed the Conference that Ireland has deposited its instrument of ratification, which would take effect on 1 August 1992 (Report 7373/92, pp. 7-8, para. 9). See, also, the opinion of **John Neukon**, What Price the Community Patent?, [1992] 4 *EIPR* 111-112.

This Chapter intends to analyse the Community Patent Convention, although not yet in force[20], in so far as it is the Convention for the purposes of unifying national patent laws in the EC. The European Patent Convention - which is a Convention for the granting of patents with the same effect as a national patent for each of the Contracting State designated in the application (consisting in a "bundle of national patents"), involving not only EC Member States, but with a broader scope - is very closely related with the CPC and will be partially analysed within the context of the Community Patent Convention.[21] With a more descriptive approach, this Chapter studies primarily the aspects dealing with institutional arrangements, patentable subject-matter, substantive patent law and the establishment of a common system of jurisdiction and enforcement, under the auspices of the CPC.

1. GENERAL CONSIDERATIONS

The creation of a patent system for the Community was historically envisaged alongside the creation of a parallel broader system for Europe, established by the European Patent Convention. The CPC, however, is not intended to replace either national patents or "European patents"[22]. All these systems of law will work in harmony[23]. The main

---

[20]In accordance with Article 10 of the Agreement, the CPC shall enter into force on the first day of the third month after the last State had made the deposit of the instrument of ratification.

[21]For a detailed study of the laws and practices of the EPC, see **Gerald Paterson**, note 9, *supra*. Also, as a historical reference on the analysis of the provisions contained in the EPC, see **M. van Empel**, note 7, *supra*, and **Friedrich-Karl Beier**, The European Patent System, (1981) 14 *Vanderbilt Journal of Transnational Law* 1-16.

[22]For the purposes of definition, patents granted under the EPC shall be called "European patents" (EPC, Art. 2 (1)) and patents granted under the CPC shall be called "Community patents" (CPC, Art. 2 (1)). Obviously, "national patents" are patents granted by national patent offices of the Contracting States.

[23]CPC, Arts. 1 (2) and 5. Further, it is worth noting that, through the experience of the European Patent Convention, it may be predicted that the CPC would replace in the long term the national patents granting procedures. The European Patent Office, within a short period of time, has achieved a great level of activity, being in a position of dominance even before the largest national patent offices (**Jenõ Staehelin**, The European Patent Organisation, [1981] 1 *YEL* 333-346, p. 346).

difference between these systems is that national patents are granted with a specifically national territorial scope, while the applicant for a European patent may designate in which Contracting States of the EPC he wishes his invention to be protected[24]. Community patents, on the other hand, shall have a "unitary and autonomous effect"[25]. It means that Community patents will have effect throughout the whole territory of the Community and "... may only be granted, transferred, revoked or allowed to lapse in respect of the whole of such territories"[26]. Unlike European patents, a Community patent can only be granted for the whole of the territory of the Community and the designation of one Member State of the EC is considered as comprising them all.

It is argued that the CPC is the most ambitious system of all:

> In effect it sets out to create a unitary system of patent law which in each EEC member State will govern the whole life of the patent, from the filing the application to the grant of the patent and after grant of the patent to the conditions under which the patent is maintained in force and exploited.[27]

The main goal of the CPC is "the elimination within the Community of the distortion of competition which may result from the territorial aspect of national protection rights"[28] and which would create obstacles to the free movement of goods. Community patents shall also have the same effect as a national patent granted by national law of the Member States[29], having equal effect throughout the territories of the Community.

---

[24]EPC, Art. 3.
[25]The Agreement, Preamble, and CPC, Art. 2.
[26]CPC, Art. 2 (2). Under the wording of this paragraph it shall also be understood that when a territory of the Community is designated for the purposes of a European patent, the same unique character of the patent will apply.
[27]**Jenõ Staehelin**, note 23, *supra*, p. 334.
[28]The Agreement, Preamble.
[29]CPC, Art. 38.

Pursuant to Article 8, the Agreement also permits that a State party of the EPC, "... which forms a custom union or a free trade area" with the EC, could participate in the Agreement after a unanimous decisions of the Council. Here, the "enlargement" of the European Community is clearly envisaged.

The Convention itself is a special agreement within the meaning of Article 142 of the EPC, a regional patent treaty within the meaning of Article 45 (1) of the PCT, and a special agreement within the meaning of Article 19 of the Paris Convention.

2. *INSTITUTIONAL ARRANGEMENTS*

The EPC has established a European Patent Organisation comprising two organs: a European Patent Office (EPO) and an Administrative Council.[30] The CPC, on the other hand, will establish, under the auspices of the EPO, a Patent Administration Division and one or more Revocation Divisions[31].[32] Also, under the Administrative Council of the EPO, the Community system will establish a Select Committee composed of representatives of the Contracting States, the representative of the Commission of the European

---

[30]EPC, Art. 4.

[31]CPC, Art. 6. These "special departments" shall be responsible exclusively for acts relating to Community patents and the official language of these departments shall be the official languages of the EPO (CPC, Art. 10) *i.e.*, English, French and German (EPC, Art. 14). Regarding European patents, the departments in charge are a Receiving Section; Search Divisions; Examining Divisions; Opposition Divisions; a Legal Division; Boards of Appeal; and an Enlarged Board of Appeal (EPC, Art. 15). The tasks of these departments are beyond the scope of this Chapter. It will be referred to only when in relation to the CPC.

[32]In the wording of the first version of the CPC, signed in 1975, there should also be one or more Revocation Boards (CPC 1975, Art. 7 (c)), with the task of examining appeals from the decisions of the Revocation Divisions and from the Patent Administration Division, and of expressing opinions on the extent of protection of a Community patents (CPC 1975, Art. 10). The developments of this Convention, brought up by the Agreement, excluded the latter and its tasks were transferred to the Common Appeal Court (COPAC), established by the "Protocol on the Settlement of Litigation concerning the Infringement and Validity of Community Patents" (OJ 1989 L401/34).

Communities and their alternate representatives. The same members shall represent the Contracting States on the Administrative Council and on the Select Committee[33].

The language of the proceedings before those special departments established by the CPC, in accordance with Rule 3 (1) of the Implementing Regulations of the CPC, shall be as provided by Rules 1 to 3, 5, 6 (2) and 7 of the Implementing Regulations of the EPC. Also, in accordance with Implementing Regulations of the CPC (Rule 2 (2)), the special departments may be grouped together administratively with other departments of the EPO so as to form Directorates-General.

The Patent Administration Division shall have administrative responsibilities relating to Community patents which are not the responsibility of other departments of the EPO. In particular, the Division will have the task of deciding the entries in the Register of Community Patents[34]. The President of the EPO shall, with the agreement of the Select Committee of the Administrative Council, determine in detail the duties of the Patent Administration Division[35].

The Revocation Divisions shall have responsibilities for the examination of requests for the limitation of and applications for the revocation of Community patents and, also, for determining, under Article 43 (5) of the CPC, appropriate compensation for the purposes of licenses of right, when one of the parties requests it[36]. The number of Revocation Divisions, as well as the allocation of duties of each, shall be determined, exclusively, by the President of the EPO[37].

The Administrative Council is empowered to amend time-limits laid down by the CPC, which are to be observed in relation with the EPO. Also the Administrative Council

---

[33]CPC, Art. 11.
[34]*Ibid.*, Art. 7 (1). The Register of Community patents is established by Article 63 of the CPC.
[35]Implementing Regulations of the CPC, Rule 1 (2).
[36]CPC, Art. 8 (1).

may amend its Implementing Regulations[38], and adopt or amend the Financial Provisions, the Rules relating to Fees and its Rules of Procedure[39]. It is also empowered to take decisions relating to budgetary matters[40].[41]

3. PATENTABLE SUBJECT-MATTER

In the wording of Article 32 (2) of the Protocol, the patentable subject-matter of inventions under the CPC will be as provided by Articles 52 to 57 of the European Patent Convention. However, if a Member State of the Community is not a Contracting Party of the EPC, the national court, acting as a Community patent court, shall apply its national law, in accordance with the international agreements of which the Contracting State is part[42]. The provisions relating to patentable subject-matter, as established by the EPC, are essentially in conformity with the provisions of the "Strasbourg Convention"[43].

3.1. The basic requirements

A Community patent will be granted to "... any inventions which are susceptible of industrial application, which are new and which involve an inventive step"[44]. The EPO will firstly consider these "positive requirements" of novelty, inventiveness (or obviousness) and industrial application (usefulness), and, then, the "negative requirements" (exclusions and exceptions) provided by Articles 52 (2) and 53 of the EPC will be considered. The

---

[37]Implementing Regulations of the CPC, Rule 1 (1).
[38]CPC, Art 16 (1) (a) and (b), respectively.
[39]*Ibid.*, Art. 16 (2) (a), (b) and (c), respectively.
[40]*Ibid.*, Art. 21.
[41]For a more comprehensive outline of the inter-action between institutional structures of the EPC and the CPC, see Appendix III.
[42]Paragraph 2 of Article 32 of the Protocol rules: "On all matters not covered by the Agreement relating to Community Patents a Community patent court shall apply its national law, including its private international law".
[43]Note 9, *supra*.
[44]EPC, Art. 52 (1).

requirements of novelty, inventiveness and industrial applicability are generally provided by all national systems of the participating countries of the Community and, at first sight, does not raise further conflicts.

The first requirement, that there should be an invention, was mostly dealt with by the Boards of Appeal of the EPO together with the analysis of the provision of excluded patentable subject-matter, in Article 52 (2) of the EPC. It is also undertaken that the assessment to this requirement should be considered separately from the requirements of industrial application and inventiveness. It is worth mentioning that the EPC does not attempt to define what should be understood by the term "invention", leaving this problem to national courts which will consider a juridical definition of invention taking into account the positive and negative requirements of national laws and practices.

The requirement that an invention must be new, although generally settled by national laws, has been developed quite differently under the EPC. The need of such requirement could have been questioned since the assessment of the inventiveness of the invention seems to be within the subject-matter of a patent, and its concept appears to be closely related to the concept of novelty.[45]

Firstly, in order to clarify the distinction between the concepts of novelty and inventive step, it is necessary to describe further the concept of the "state of the art". Article 54 (1) of the EPC states that "[a]n invention shall be considered to be new if it does not form part of the state of the art". Then, Article 54 (2), EPC, affirms that "... everything made available to the public by means of written or oral description, by use, or

[45]The Enlarged Board of Appeal of the EPO attempted to clarify the distinction between both concepts - novelty and inventiveness - in Decision G2/88 (MOBIL OIL/Friction reducing additive), [1990] EPOR 73, stating that "... information equivalent to a claimed invention may be 'made available' [lack of novelty], or may not have been made available but obvious [new, but lack of inventiveness], or not made available and not obvious [new and non-obvious]. Thus, in particular, what is hidden may still be obvious".

in any other way, before the date of filing of the European patent application" is comprised in the state of the art. For the purposes of the application of this provision there is, thus, no requirement that a "...member of the public actually received the information about the invention. What matters is whether such information was made available"[46]. Thereupon, it does not matter in which language the information was made available, "[t]he scale on which information has been made available to the public ..."[47], the territory in which the information was made available to the public, the period of time that the information was made available, and by which means the information was made available, before the filing of an European patent application. If anyone of the public could have had access to the information, the invention will be already included in the state of the art and will lack novelty.[48]

In relation with the means by which an invention was made available to the public, there are at least three circumstances which must be considered. Firstly, Article 54 (2) of the EPC affirms that an invention will be deemed as comprised in the state of the art by any means if it has been made available to the public by written or oral description, by use or by any other means. When an invention is made available to the public by a written description it will be considered as in the state of the art if a document containing the

---

[46]**Gerald Paterson**, note 9, *supra*, p. 373, para. 9-05.

[47]*Ibid.*, p. 373, para. 9-08. See, also, Decision T381/87 (RESEARCH CORPORATION/Publication), [1989] EPOR 138, where it was held that the simple fact of placing a copy of a document on the shelves of a library includes information in the state of the art. In Decision T482/89 (TÉLÉMÉCANIQUE/Electrical Supply) 11 December 1990 (*apud* **Gerald Paterson**, note 9, *supra*, para. 9-16) it was held that one single sale of a product would be enough to include the information as having been made available to the public.

[48]Note, additionally, that there is a distinction between "absolute" and "relative" novelty. **Douglas Gabriel Domingues**, Direito Industrial - Patentes, Rio de Janeiro: Companhia Editora Forense (1980), at p. 37, quoting **Henry Allart**, Traite Théorique et Pratique des Brevets d'Invention, affirms that the concept of "absolute novelty" should be understood as when an invention is considered part of the state of the art if it has been made available, by any means, anywhere in the world. The concept of "relative novelty", on the other hand, includes the understanding that an invention will be considered within the state of the art if it was made available only in the territory of the State in which such a law applies, within a limited time. In the EPC, the "absolute novelty" concept is the

written description of the invention has been placed somewhere to which the public has access, such as a library[49].

With regard to an oral disclosure of an invention, the question becomes more complex if there is no record of such event. If the invention was made available to the public by oral description and such a description was somehow recorded, thus proving that sufficient disclosure took place, the evaluation of the disclosure will be made much easier for a patent office.

The disclosure of the technical features of an invention by use is essentially based on a prior use of the invention which has been visible to members of the public[50], or a prior sale of the product has occurred. It is also possible to argue that "[i]n cases of alleged prior use, a product or process may have been used in public, but it may still have to be decided in each individual case whether such use has made the technical features of the claimed invention available to the public and thus part of the state of the art"[51].

The EPC has also established, in Article 54 (3), the concept of "prior right". This means that when a European patent application has been filed before a second European patent application, but the first was published after the second patent application, the second patent application will be part of the state of the art and will be lacking novelty. It is necessary to say that this "legal fiction" created by the EPC applies only for the

---

one provided, as far as it does not matter when and where the invention was made available to the public to be included in the state of the art.

[49]See, *e.g.*, Decision T381/87, note 47, *supra*.

[50]See, *e.g.*, Decision T84/83 (LUCHTENBER/Rear-view mirror) [1979-85] EPOR: C: 796.

[51]**Gerald Paterson**, note 9, *supra*, p. 413. See, also, for further consideration concerning the prior use of claimed inventions, Decision T482/89, note 47, *supra*, Decision T93/89 (HOECHST/Polyvinyl ester dispersion) 15 November 1990, *apud*, **Gerald Paterson**, note 9, *supra*, paras. 9-17 and 9-19, and Decision T301/87 (BIOGEN/Alpha-interpherons) [1990] EPOR 190.

examination of novelty, and will not be used when examining the inventiveness of a patent application.[52]

The considerations of the requirement of inventiveness will be taken into account if the invention was firstly not considered as being part of the state of the art, as above described. Thus, Article 56 of the EPC states that, "if, having regard to the state of the art, it [the invention] is not obvious to a person skilled in the art" the invention in question will meet the requirements of inventiveness. The assessment of inventiveness considers, thus, that a particular invention had some technical features which are "... not open to the average or ordinary mind"[53]. In addition, it is important to note that the date at which the state of the art has to be determined for inventive step is the filing date. The filing date, in this case, has to be considered either as the actual date of filing the application or, pursuant to Article 89 of the EPC, regarding the right of priority under Article 87 of the EPC[54].

For assessing the inventiveness of inventions the EPO had to develop, through its practice, consistency in defining the way in which inventiveness would be recognised. This should lead to legal certainty and reliability for users of the EPO. The general approach to assess such requirements would take into account, firstly, "... the necessity to take all relevant facts which were available, in the sources, to the skilled person, and survey the relationship of each of these to the invention, before trying to find reasons, if any, to

---

[52]See, for further discussion about this matter, **Gerald Paterson**, note 9, *supra*, pp. 386-389, paras. 9-31 to 9-36.

[53]**William Cornish**, The Essential Criteria for Patentability of European Inventions: Novelty and Inventive Step, [1983] 6 *IIC* 765-775.

[54]In Decision T24/81 (BASF/Metal refining), [1974-85] EPOR: B: 414, the Technical Board of Appeal affirmed that "[w]hen examining for inventive step, the state of the art must be assessed from the point of view of the man skilled in the art at the time of priority relevant for the application". For further details on the application of the "right of priority" concept, see, *supra*, Chapter 2, Section 1, Sub-section 1.1, Paragraph 1.1.2.

combine them to generate the claimed subject-matter"[55]. The EPO, on the other hand, has considered a quite different approach, described as follows:

> The approach tries to retrace the possibilities according to which the skilled person could consider changes in technology in a non-inventive manner. It recognises that he might be prompted by an available source purely by chance and assumes that, if interested, he would be in a position to formulate technical problems and try to solve any one of them by searching for features which could modify his primary state of art to provide the desired effects. He would carefully balance the arguments for and against such modifications in the light of all technical circumstances and of his common general knowledge. If the reasons are clearly overwhelmingly in the direction of generating the invention as a solution of the problem, he may even find it worthwhile to try out a promising combination.[56]

The so-called "problem-and-solution" approach seems to be working satisfactorily as a method of assessing inventiveness of inventions in the EPO context. This has, in one sense, provided national courts with more grounds of decision when deciding upon a dispute which includes the validity of a patent application.

In the wording of Article 57 of the EPC, the requirement of the susceptibility of industrial application must be understood as such: "... if it can be made or used in any kind of industry, including agriculture". The questions on industrial applicability have arisen mostly in the discussions of the results of pharmaceutical or biological processes[57]. It seems that, in general, there is not much controversy on the application of the issues on industrial applicability.

---

[55] **George S.A. Szabo**, The Problem and Solution Approach in the European Patent Office, [1995] 4 *IIC* 457-487, at 460.

[56] *Ibid.*, at 487.

[57] A number of decisions have been examining the assessment to this requirement on the discussions of the patentability of pharmaceutical and biological processes. In particular, see Decisions T144/83 (DU PONT/Appetite suppressant), [1987] EPOR 6; T36/83 (ROUSSEL-UCLAF/Thenoyl peroxide), [1987] EPOR 1; and T385/86 (BRUKER/Non-invasive measurement) [1988] EPOR 357.

3.2. The negative requirements

It was said in the foregoing Sub-section that there are also some negative requirements which must be considered for assessing the patentability of the invention. It means that if a patent application falls within one of the prohibitions which are described in this Sub-section, an invention would not be patentable.

Articles 52 and 53 of the EPC list the types of subject-matter which are not patentable. Paragraphs (2), (3) and (4) of Article 52 expressly exclude from patentability subject-matter which are not to be considered inventions. Further, Article 53 lists the exceptions of what may be considered inventions, even meeting the positive requirements, but which shall not be patentable by a decision of the law. This Sub-section will provide a brief view of both issues. Part 1 of Chapter 5, below, provides more discussion on this matter.

Under the wording of Article 52 (2) of the EPC, the following are, particularly, excluded from patentability, not being regarded as inventions:

> (a) discoveries, scientific theories, and mathematical methods;
> (b) aesthetic creations;
> (c) schemes, rules and methods for performing mental acts, playing games or doing business, and computer programs;
> (d) presentations of information.

Article 52 goes further and states, in paragraph 3, that the subject-matter or activities referred to in paragraph 2 are excluded from patentability to the extent to which an European patent application or an European patent relates to the subject-matter or activities "as such".

Paragraph 4 of Article 52 also excludes from patentability the subject-matter of "[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body ...". However, this will not apply to "... products, in particular substances or compositions, for use in any of these methods".

The discussion of this item should address, more carefully, two specific exclusions: the patentability of computer programs and methods for treatment of the human or animal body.

In relation to computer programs, it must be noted that computer software *per se* is excluded from patentability. The discussion of a possible patent for computer program, however, is focused on the computer software which is an essential part of an invention, *i.e.* inventions which would not work without the attached software. The German Federal Court of Justice, in its Decision in *Flugkostenminimierung*[58], interprets this type of exclusion in such a way that computer programs may be patentable in some circumstances. The EPO, under its Decision T208/84[59], understood that computer software *per se* is excluded from patentability in the light of Article 52 (2) (c) of the EPC, and should not be patentable even in the context of a whole process of an invention. Considering, nevertheless, that Article 52 (3), EPC, rules that the exclusions set up in paragraph 2 are addressed specifically to the patentable subject-matter or activities, only to the extent which a European patent application or a European patent relates to such subject matter

[58]BGH Case N. XZR 65/85 GRUR 1986, 531, *apud* **Gerald Paterson**, note 9, *supra*, at p. 318, note 15.

[59]T208/84 (VICOM/Computer-related invention), [1986] EPOR 74.

or activities as such, it would be possible to hold that a computer software should be patentable as within the whole of an invention[60].

In relation to methods for treatment of the human or animal body by surgery or therapy, it should be noted that the methods themselves are excluded from patentability, but the products for use in any of these methods are not. At the Intergovernmental Conference preceding the EPC it was proposed that such methods should not be excluded from patentability. For ethical reasons this issue was excluded from patentability in the EPC, however. In addition, at that time most European countries provided for the exclusions of such methods in their national legal systems. Decisions in the EPO have discussed such an exclusion but none of them came before the Boards of Appeal to consider treatment by surgery itself.[61]

Article 53 of the EPC, on the other hand, lists the exceptions to patentability as follows: (a) inventions contrary to the morality or to the *ordre public*, and (b) plant or animal varieties or essentially biological processes for the production of plant or animal varieties.

In relation to the first item, the Board of Appeal has had to interpret it only once.[62] It seems again that the purpose of the EPC was the creation of reasonably ethical limits for inventions. In the HARVARD/Onco-mouse case[63] the issues arose in the sense that the genetic manipulation of animals is as dangerous as the genetic manipulation of human beings, in so far as the patentability and further commercialisation of the results of such

---

[60]See, generally, Decisions T208/84, note 59, *supra*, and T115/85 (IBM/Computer-related invention), [1990] EPOR 107.

[61]See, *e.g.*, Decisions T603/89 (BEATTIE/Marker) 3 July 1990 (P), *apud* **Gerald Paterson**, note 9, *supra*, para. 7-23; G5/83 (EISAI/Second medical indication), [1979-85] EPOR: B: 241; T116/85 (WELLCOME/Pigs I), [1988] EPOR 1; and T385/86 (BRUKER/Non-invasive measurement), [1988] EPOR 357. For further analysis on this issues, see **Gerald Paterson**, The Patentability of Further Uses of a Known Product under the European Patent Convention, [1991] 1 *EIPR* 16-20.

[62]Decision T19/90 (HARVARD/Onco-Mouse), [1990] EPOR 50.

genetic manipulation involve several ethical controversial issues which have not been concluded so far.[64]

The analysis of the exclusions of plant and animal varieties takes another approach. At the time of the creation of the EPC the importance of biotechnology was not as much as it is today. The EPC, therefore, makes no difference between plants and animal varieties and treats both of them as living forms. At the time that the EPC came into force, living matters were generally not subject to IPRs. With the developments of biotechnology and, consequently, of international law[65], the EPO will face different, and probably more complex, challenges.

3.3. Selected issues

All issues on patent protection in the EC are worth mentioning. In this Chapter, like Chapter 5, I have chosen three specific matters that might, or might not, fall within the patent protection field. The discussion that follows is related to the necessary mechanisms which, within a Common Market, has played a determinant part in the setting up of necessary rules for the functioning and proper operation of the common area integrated by the EC Treaty.

---

[63] *Ibid.*

[64] *Cf.* note 104, *infra*, for further reference on the ethical dimension of the protection of biotechnological inventions.

[65] See, for instance, further discussion in the international arena in Chapter 5, Part 2, *infra*. The issues on biotechnology patenting in Europe is also discussed in more detail in Sub-section 3.3, *infra*.

3.3.1. Pharmaceutical products and processes

Several fundamental issues have arisen from the application of the provisions of the EPC for the protection of pharmaceutical products and processes. In addition, in the EC context another relevant matter has been implemented in relation to the extension of term of protection for pharmaceutical products. These are the two subjects of this Paragraph.

As has been seen, the EPC, in Article 52 (4), excludes from patentability methods for treatment of the human or animal body. Article 52 (4) also provides for an exception to this rule when it says, in the last sentence, that substances or compositions for use in any of these methods will be considered inventions[66]. Additionally, Article 54 (5), last sentence, EPC, considers that substances or compositions which are already part of the state of the art, but where the use is not comprised in the state of the art, will be patentable, and not considered as lacking novelty.

This special proviso states that where the subsequent use of a pharmaceutical product which is patented was not considered in the patent application, the new use will be capable of patent protection. This, in the light of the legislative history of the EPC, appears to be within the necessary justification for patent protection of pharmaceuticals which would reward the inventor for contributing to the state of the art and, therefore, benefiting the general public with new properties of known pharmaceutical inventions. In this context, it is assumed that only the first indication is

---

[66]Note, in addition, that Article 167 of the EPC permitted signatory States to make a reservation to withhold patent protection for pharmaceutical products, subject to a limit of ten years from the entry into force of the EPC (7 October 1977). The Administrative Council could extend this period by five years.

protected, but not further and consequent uses of the invention. This is the approach taken by the EPO, which has raised controversial viewpoints[67].

Particularly in the EC a legal mechanism has been discussed and implemented to provide pharmaceutical patents with a "restoring" mechanism for the duration of their lives. Considering that pharmaceutical products are the outcome of costly and time-consuming research, being also subject to governmental approval before marketing, the EC has issued a Council Regulation concerning the creation of a supplementary protection certificate for medicinal products[68]. The SPC Regulation applies to "[a]ny product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure ..."[69].

Such protection will confer the basic rights as conferred by the original patents, being subject to the same limitations and obligations, as applied to the original patents[70]. It is assumed that the rights conferred by the SPC is a right in addition to the patent right, but not an extension of the patent term[71]. The SPC will have effect for a maximum period of five years. Such a five year period takes into account the end of the original patent term for a period equal to the period which elapsed between the date on which the application of a basic patent was filed, and the

---

[67] See, for more exhaustive analysis of the protection of the first, second and subsequent use of a known pharmaceutical product, **Werner Stieger**, Article 54 (5) of the Munich Patent Convention: An Exception for Pharmaceuticals, [1982] 2 *IIC* 137-161, and **Gerald Klöpsch**, The Patentability of Pharmaceuticals According to the European Patent Convention (EPC), [1982] 4 *IIC* 457-470.

[68] Regulation N. 1.768, of 18 June 1992 (OJ 1992 L182/1). Hereinafter the "SPC Regulation".

[69] SPC Regulation, Art. 2.

[70] SPC Regulation, Art. 5.

[71] See, *e.g.*, **John Adams**, Supplementary Protection Certificates: the Challenge to EC Regulation 1768/92, [1994] 8 *EIPR* 323-326.

date that the governmental authorisation to market the medicinal product[72] took place[73].

To apply for a Supplementary Patent Certificate (SPC) there must be in existence a product protected by a original patent in force, with a valid authorisation to place the product in the market granted in accordance with the Community rules[74], and the product in question must not have been the subject of a certificate before.[75]

The SPC will be granted to the original holder of the patent or to his successors in title[76], by the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted[77]. The procedures will be determined by the national procedural provisions dealing with the granting of patents[78], and the possibility of review of the decisions granting or refusing the SPC shall be available[79].

3.3.2. Biotechnology

Biotechnology and plant varieties protection are discussed in the text of the EPC in a single provision, but will be discussed here separately, under two headings. The EPC in Article 53 (b) affirms that, though they may be considered inventions, patent

---

[72]For the purpose of the application of the SPC Regulation, the following definitions, in particular, shall be considered: "(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;" and "(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product" (SPC Regulation, Art. 1).

[73]SPC Regulation, Art. 13.

[74]The Community rules in question are Directive N. 65/65 (OJ 1965 L22/369), last amended by Directive N. 341/89 (OJ 1989 L142/11), and Directive N. 851/81 (OJ 1981 L317/1), last amended by Directive N. 676/90 (OJ 1990 L373/15).

[75]SPC Regulation, Art. 3.

[76]*Ibid.*, Art. 6.

[77]*Ibid.*, Arts. 9 (1) and 10.

[78]*Ibid.*, Art. 18.

protection shall not be granted to "plant or animal varieties or essentially biological processes for the production of plants or animals". Later in the same provision the EPC concludes that "... this provision does not apply to microbiological processes or the products thereof"[80].

Several questions arise from the application of this rule. Firstly, a definition of neither animal varieties, nor plant varieties is settled. Only vague ideas existed in relation with the interpretation of what appears to be the meaning of "essentially biological processes" and "microbiological processes". The EPO has in several decisions tried to develop such concepts and bring some legal certainty to patent applicants.

Probably the most controversial decision on the biotechnology field, and the one which has raised much attention in the media, has been a result of a patent application for a "... method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms". The said method comprises the introduction of "... an activated oncogene sequence into a non-human mammalian animal at a stage no later than the 8-cell stage"[81]. Claim 17 of the said invention went further saying that the applicant wanted protection also for "[a] transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated sequence introduced into said animal, or an ancestor of the said animal, at a stage no later than the 8-cell stage, ..."[82].

---

[79] *Ibid.*, Art. 17.

[80] It is also important to note that the wording of Article 53 (b) of the EPC was used as a basic reference for the drafting up of the text of the TRIPS Agreement of the Uruguay Round of GATT. *Cf.* Chapter 5, Part 2, Section 2, Sub-section 2.1, Paragraph 2.1.2, *infra*.

[81] Claim 1 of the invention, as quoted in, Examining Division, Application 85 304 490.7 of 14 July 1989 (HARVARD/Onco-mouse), [1990] EPOR 4, at p. 6.

[82] *Ibid.*, Claim 18 has also applied for protection of "[a]n animal as claimed in Claim 17 which is a rodent".

In relation to the definition of "animal varieties", the Examining Division of the EPO has considered that, at the time that the text of the EPC was drafted, legislators had not in mind the question of patenting a transgenic animal, because modern methods of genetic engineering were then at a very early stage. The EPO has considered that, in contrast to the definition of "plant varieties" which will be discussed further in Paragraph 3.3.3, below, the definition of an animal variety, though vague, had to be understood "... to be the result of the mere breeding of animals"[83]. In this case, Claims 17 and 18 of the application were understood as containing process features which, in the view of the Examining Division, "... are concerned with the mere breeding of animals, namely animals which already have the oncogene incorporated in their genome"[84]. It seems that so far a clear definition of what should be understood by an "animal variety" has still to emerge from the EPO case-law. The HARVARD/Onco-mouse case, which has not been finally decided yet[85], does not give much detailed interpretation on how to solve the problem of definition of "animal variety".

In relation to the definition of "essentially biological process", the EPO has, apparently, concluded that such a term should be understood as a process which has not undergone any intervention through human research. In this case, as clearly established by Article 53 (b), EPC, the subject-matter of a patent application is not capable of protection. In the HARVARD/Onco Mouse case, the Examining Division has understood that the essence of this patent application is "... the introduction of an oncogene into an animal by technical means, for example, micro-injection". It has

---

[83] *Ibid.*, p. 8.
[84] *Ibid.*.

obviously concluded that some technical intervention was made and that such a claim would not fall within the prohibition of Article 53 (b), EPC.

In relation to the definition of a "microbiological process", which is not excluded from patentability by virtue of the last sentence of Article 53 (b), EPC, the Examining Division has firstly concluded that this part of the provision had to be interpreted together with the exception in the first sentence of Article 53 (b). Thus, if a product falls within the prohibition of the first sentence, a side interpretation of the last sentence could not apply. Following this path, the Examining Division has concluded that processes producing plant or animal varieties in the sense of the first sentence are not to be regarded as micro-biological processes, and, therefore, "[t]his seems to be quite in conformity with scientific terminology which uses microbiology in relation to microorganisms and biology in relation to plants or animals even at the cellular stage"[86].

It seems however that all such definitions are not clearly established in a general basis, and that the EPO will consider case-by-case to assess the input given by the text of the Convention.

In addition to that, it is also worth mentioning that a proposed directive for the protection of biotechnological inventions was issued by the Commission in October 1988[87], attempting to harmonise national legislation on the patentability of plants and animals. This proposed directive, which was supposed to provide greater incentive to the biotechnology industries in the Community, was refused by the European

---

[85]This case has been further submitted to the Technical Board of Appeal of the EPO (T19/90 (HARVARD/Onco-mouse), [1990] EPOR 501) and will be decided, probably, after a decision of the Enlarged Board of Appeal.

[86]Application 85 304 490.7 of 14 July 1989 (HARVARD/Onco-mouse) note 81, *supra*, p. 9.

[87]Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, OJ 1993 C44/36.

Parliament on 1 March 1995. The envisaged route that follows the non-approval of the directive is that the EPO will continue to analyse case-by-case the patentability of biotechnological inventions, as well as national patent offices, in accordance with their respective legal basis.[88] It appears that, after several modifications of the original proposal took place during the legislative process of this directive, part of the biotechnology industry in Europe considered that the decision of the European Parliament was not entirely unsatisfactory to European biotechnology industry in so far as the "... proposal had, in its final form, been watered down to such an extent that it would anyway have been of limited use to industry"[89].

The Commission eventually re-issued another "Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions", on 13 December 1995[90]. The Proposed Biotechnology Directive, recognising that biotechnology and genetic engineering research is of fundamental importance for the Community's industrial development and is surrounded by high investments and risks, affirms that the possibility for researchers to recoup those investment is through effective and harmonised protection of biotechnological inventions throughout the Community[91].

The Proposed Biotechnology Directive is composed of a Preamble with thirty three Recitals, and twenty Articles. The main goal of the PBD is to make clearer the harmonised understanding that should be provided to such complex and controversial

---

[88]See, for further discussion on the proposed Commission biotechnology directive, **The Chartered Institute of Patent Agents**, Briefing Paper: The European Commission Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, *mimeo*, August 1992; **Robin Nott**, The Proposed EC Directive on Biotechnological Inventions, [1994] 5 *EIPR* 191-194; **Willi Rothley**, European Parliament Must Think Again About Biotechnological Protection, [1995] 5 *IIC* 668-670.

[89]**Thomas C. Vinje**, Harmonising Intellectual Property Laws in the European Union: Past, Present and Future, [1995] 8 *EIPR* 361-377, p. 367.

[90]COM(95) 661 final, pp. 26-34. Hereinafter the "Proposed Biotechnology Directive" or the "PBD".

concepts and principles in the field of legal protections of biotechnological inventions. For this purpose, the Proposed Biotechnology Directive begins by suggesting, in Article 1, that biotechnological inventions must be protected by national laws of the Member States[92] and that the PBD will not prejudice national and Community laws on the control and monitoring of research and further commercialisation of the result of research[93]. It also defines the concept of "biological material"[94], "microbiological process"[95] and "essentially biological process for the production of plants and animals"[96].

Biotechnological inventions which are new, the result of an inventive step and industrially applicable, are, in general terms, capable of protection[97]. Particularly the following will be patentable: biological material[98], microbiological processes and products obtained by means of such process[99], and uses of plant or animal varieties for their production[100]. The Proposed Biotechnology Directive explicitly excludes from

---

[91]PBD, Recitals (1), (2) and (3).
[92]*Ibid.*, Art. 1 (1). If necessary, Member States are required to adapt their national patent laws to the provisions of the Proposed Biotechnology Directive.
[93]*Ibid.*, Art. 1 (2).
[94]*Ibid.*, Art. 2 (1). "'[B]iological material' means any material containing genetic information and capable of self-reproduction or of being reproduced in a biological system".
[95]*Ibid.*, Art. 2 (2). "'[M]icrobiological process' means any process involving or performed upon or resulting in microbiological material; a process consisting of a succession of steps shall be treated as a microbiological process if at least one essential step of the process is microbiological".
[96]*Ibid.*, Art. 2 (3). "'[E]ssentially biological process for the production of plants or animals' means any process which, taken as a whole, exists in nature or is not more than a natural plant-breeding or animal breeding process".
[97]National legislation must not consider the subject-matter of a biotechnological invention unpatentable only because "... it is composed of, uses or is applied to biological material" (PBD, Art. 4 (1)). Note, in addition, that the subject of an invention concerning a biological material must not be considered a discovery or lacking novelty only because this is already part of the natural world (*Ibid.*, Art. 8). Article 8 of the PBD "... merely emphasizes the need for an invention to be a technical solution to a technical problem" (COM(95) 661 final, note 90, *supra*, p. 18, para. 66).
[98]PBD, Art. 4 (2). This includes "... plants and animals, as well as elements of plants and animals obtained by means of a process not essentially biological, ..." and excludes "... plant and animal varieties as such, ...".
[99]*Ibid.*, Art. 5.
[100]*Ibid.*, Art. 7.

patentability the following: the human body and its elements in their natural state[101], essentially biological processes for the production of plants or animals[102], and where its exploitation would be contrary to public policy or morality[103]. The latter situation is particularly to be viewed as "... a genuine reflection of the ethical dimension of biotechnological inventions"[104].

With regard to the scope of protection, the Proposed Biotechnology Directive suggests that the protection conferred by a patent on a biological material possessing specific characteristics, as a result of the invention, and the protection conferred by a patent that enables biological material to be produced possessing specific characteristics "... shall extend to any biological material derived from that biological material through multiplication or propagation in an identical or divergent form and possessing those same characteristics"[105].

With regard to the scope of legal protection of biotechnological inventions, the Proposed Biotechnology Directive also suggests the following derogation: (a) once a patent holder, or someone with his consent, sells a propagating material to a

---

[101]*Ibid.*, Art. 3 (1). However, an element which has been isolated from the human body or otherwise produced by means of a technical process will be patentable, even if the structure of the element in question is identical to that of a natural state (*Ibid.*, Art. 3 (2)).

[102]*Ibid.*, Art. 6.

[103]*Ibid.*, Art. 9 (1). Note, additionally, that such exploitation shall not be deemed contrary to either public policy or morality only because it is prohibited by law. This seems to imply that the expression "would be contrary to public policy or morality" will be decided in a case-by-case basis. Moreover, Article 9 (2) of the PBD lists two particular situations which are to be considered unpatentable: (a) methods of human treatment involving germ line gene therapy ("*i.e.* therapy that could alter reproductive cells capable of transmitting genetic material to descendants", as suggest by COM(95) 661 final, note 90, *supra*, p. 18, para. 67), and (b) processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, or if the suffering or physical handicap of such animals are not proportionate to the objective pursued.

[104]COM(95) 661 final, note 90, *supra*, p. 18, para. 67.

[105]PBD, Arts 10 (1) and (2). Moreover, Article 11 of the PBD emphasises that the protection conferred by a patent on a product which contains or consists of genetic information must extend to all material in which the product is incorporated. The scope of protection of biotechnological inventions within the EC will not apply, however, for biological materials obtained from the

farmer for agricultural use, such sale implies the authorisation to the farmer to use the product of his harvest for reproduction or propagation by him on his own farm[106]; and (b) the sale of breeding stock to a farmer by the patent holder or by someone with his consent implies authorisation to use the protected livestock for breeding purpose on his own farm, in order to replenish their numbers[107, 108].

The Proposed Biotechnology Directive also suggests the inclusion of compulsory licences mechanisms under the following terms. If a holder of a plant variety right cannot exploit it without infringing a biotechnological patent, he may apply for a non-exclusive compulsory licence[109]. The same applies for the holder of a biotechnology patent who cannot exploit it without infringing a plant variety right[110]. This shall be allowed, however, only if the applicant for the compulsory licence demonstrates that he tried unsuccessfully to get a licence from the patent or plant variety holder and the applicant's biotechnological invention or plant variety constitutes significant technical progress[111]. Compulsory licences will be granted by national authorities and with national territorial scope only[112].

The PBD also regulates the deposit, access and re-deposit of a biological material[113], and determines that the if the subject matter of a patent is a process for obtaining a new product, when the same product is produced by someone else, the third party's product will be considered to have been obtained by the patented

---

multiplication or propagation of biological material marketed in the territory of a Member State by the holder of the patent or with his consent (*Ibid.*, Art. 12).

[106] *Ibid.*, Art. 13 (1).

[107] *Ibid.*, Art. 13 (2).

[108] The conditions of the derogation provided by Articles 13 (1) and (2) will be established by national laws and practices (PBD, Art. 13 (3)).

[109] PBD. Art. 14 (1).

[110] *Ibid.*, Art. 14 (2).

[111] *Ibid.*, Art. 14 (3).

[112] *Ibid.*, Art. 14 (4).

[113] *Ibid.*, Arts. 15 and 16.

process[114]. It is also suggested that Member States would have to implement the Proposed Biotechnology Directive until 1 January 2000[115].

3.3.3. Plant varieties

In relation to plant varieties, as has been seen above, the text of the EPC expressly prohibits its patentability. In the European Community, however, a common system for the protection of plant varieties has been established by Regulation N. 2.100, of 27 July 1994, on Community plant variety rights[116].[117] The regime created by the CPVR Regulation shall be valid throughout the Community, solely and exclusively[118], having uniform effect within the territory of the Common Market and may be granted, transferred or terminated in this territory only in a uniform basis[119].

The application of a Community plant variety right (CPVR), which shall be without prejudice to the right of Member States to grant national property rights for plant varieties[120], applies to all botanical genera and specie including, among others, hybrids between genera and species[121]. To be entitled to a Community right a plant variety has to be distinct[122], uniform[123], stable[124], and new[125]. Applicants entitled to

---

[114]*Ibid.*, Art. 17.
[115]*Ibid.*, Art. 18 (1).
[116]OJ 1994 L227/1. Hereinafter the "CPVR Regulation". By virtue of Article 118 (1), the CPVR Regulation entered into force on 1 September 1994.
[117]Variety, for the purpose of the CPVR Regulation, means "... a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right shall be met, can be: defined by the expression of the characteristics that results from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged" (CPVR Regulation, Art. 5 (2)).
[118]CPVR Regulation, Art. 1.
[119]*Ibid.*, Art. 2.
[120]*Ibid.*, Art. 3. Cumulative protection of Community and national plant variety rights or any patent for that variety, however, shall not be permitted (*Ibid.*, Art. 92 (1)).
[121]*Ibid.*, Art. 5 (1).
[122]A variety is distinct when "... it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotype, from any other

claim a CPVR are those who bred, discovered and developed the variety, including their successor in title. If more than one person did so jointly, a CPVR should be sought for jointly, and their successors are jointly entitled to claim the right. In the case of employment, the entitlement to the CPVR will be determined by the application of the national legislation to the employment relationship.[126]

To claim a variety right the applicant must be either a national of one of the Member States or a national of a member of the UPOV Convention, or be domiciled or have their seat of business or an establishment in such a State. It is also permitted for others who do not meet these requirements to apply for a CPVR, if the Commission have decided so.[127]

Once a right is granted, in accordance with the procedures established by Part Four of the CPVR Regulation, the Community plant variety holder is the one entitled to give authorisation *inter alia* for the following acts, in relation with the variety constituents or harvested material of the protected variety: (a) production or reproduction (multiplication); (b) conditioning for the purpose of propagation; (c) offering for sale; (d) selling or other marketing; (e) exporting from the Community; (f) importing to the Community; and (g) stocking for any of above purposes.[128] This shall

---

variety whose existence is a matter of common knowledge on the date of application ..." (*Ibid.*, Art. 7 (1)).

[123]Uniformity shall be understood as, "... if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characteristics which are included in the examination of distinctness, ..." (*Ibid.*, Art. 8).

[124]A variety will be understood as stable "... if the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of such cycle" (*Ibid.*, Art. 9).

[125]A variety will be deemed new "... if, at the date of application ..., variety constituents or harvested material of the variety have not been sold or otherwise disposed to others, by or with the consent of the breeder ..." (*Ibid.*, Art. 10 (1)).

[126]*Ibid.*, Art. 11.

[127]*Ibid.*, Art. 12.

[128]*Ibid.*, Art. 13 (2). See, also, Article 13 (5).

not apply to acts done privately and for non-commercial purposes, to acts done for experimental purposes or to acts done for the purposes of breeding, or discovering and developing other varieties[129]. In addition, if any material of the protected variety has been disposed of to others by the holder or with his consent, in any part of the Community, the holder's rights will be exhausted[130]. Compulsory licences are also available in respect of Community Plant Variety Rights, but only on grounds of public interest and with the approval of the Administrative Council[131].

A CPVR shall be granted for a term of twenty five years or, in the case of varieties of vine or species, for a term of thirty years, following the year of grant[132]. The Commission may also propose to the Administrative Council an extension of these terms for up to a further five years[133].

A Community Plant Variety Office (CPVO) is established, by virtue of Article 4 of the CPVR Regulation, with legal personality[134] and represented by its President[135]. The President is empowered to, *inter alia*, take the necessary steps to ensure the functioning of the Office, including the adoption of internal administrative instructions and publications of notices; to submit yearly a management report to the Commission and to the Administrative Council; to exercise power in relation with administrative and personnel management; to draw estimates of the revenue and expenditure of the CPVO; to supply information as required by the Administrative Council; and to place, before the Administrative Council, draft amendments of the

---

[129] *Ibid.*, Art. 15.
[130] *Ibid.*, Art. 16.
[131] *Ibid.*, Art. 29.
[132] *Ibid.*, Art. 19 (1).
[133] *Ibid.*, Art. 19 (2).
[134] *Ibid.*, Art. 30 (1).
[135] *Ibid.*, Art. 30 (2). The President and Vice-Presidents of the CPVO will be appointed by the Council of the European Union, from a list of candidates which is proposed by the Commission after

CPVR Regulation.[136] The CPVO may entrust national agencies with the exercise of specific administrative functions of the Office. It may also establish sub-offices in the Member States, with their consent[137]. The languages of the CPVO shall be the languages of the Community and any procedures before the CPVO may be done with any of the languages of the Community[138]. The European Court of Justice has exclusive jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the CPVO[139] and to any disputes relating to compensation for damage caused by any of the departments or servants of the CPVO in the performance of their duties[140].

An Administrative Council is also established with the duty to, *inter alia*, advise the CPVO on matters for which they are responsible, or issue guidelines in this respect; to examine the management report of the President of the CPVO and manage the Office's activities; to establish rules on working methods; and to issue test guidelines for the technical examination of plant varieties applications[141].

The Administrative Council will be comprised of one representative of each Member State and one representative of the Commission, and their alternates[142]. The Administrative Council will elect a Chairman and a Deputy Chairman for a renewable term of three years[143]. The CPVR Regulation also affirms that one or more Boards of

---

obtaining the approval of the Administrative Council of the CPVO, for a renewable term of five years (*Ibid.*, Art. 43).
[136]*Ibid.*, Art. 42.
[137]*Ibid.*, Art. 30 (4).
[138]*Ibid.*, Art. 34.
[139]*Ibid.*, Art. 33 (2).
[140]*Ibid.*, Art. 33 (4). *Cf.* Art. 33 (3).
[141]*Ibid.*, Art. 36.
[142]*Ibid.*, Art. 37 (1).
[143]*Ibid.*, Art. 38.

Appeal shall be established for deciding on appeals from decisions of the CPVO[144], consisting of one Chairman and two other members[145].

4. SUBSTANTIVE PATENT LAW: GENERAL CLAUSES

The framework of Part II of the Community Patent Convention provides common rules related to rights to the Community patent (CPC, Chapter I), the effects of the Community patent and the European patent application (CPC, Chapter II), aspects of national rights (CPC, Chapter III), the Community patent as an object of property (CPC, Chapter IV) and aspects of compulsory licences in respect of a Community patent (CPC, Chapter V). This section is intended to give a general view of the provisions on substantive patent law, under the CPC. More prominence will be given in the next section on the provisions relating to aspects of exhaustion of patent rights and compulsory licences.

The first Chapter of Part II of the CPC provides that if a holder of a Community patent is not entitled to it under Article 60 (1) of the EPC[146], the person entitled to it may claim the transfer of the patent to him[147]. Further, Article 23, CPC, stipulates a time limit of two years from the publication of the grant of the patent in the European Patent Bulletin for legal proceedings for the transfer of such a patent. This provision will not apply if the proprietor who had the patent transferred to him knew that he was not the inventor[148]. As a consequence, when the transfer of proprietorship occurs, under Article 23 of the CPC, licences and other rights shall lapse after the registration of the person entitled to the

---

[144] *Ibid.*, Art. 45 (1) and (2). *Cf.* Art. 67.
[145] *Ibid.*, Art. 46 (1).
[146] Article 60 (1) of the EPC states that the inventor, or his successor in title, is the person entitled to have the patent. Further, paragraph 1 deals with the problem of inventors who are employees and leaves the problem to be solved by national law.
[147] CPC, Art. 23 (1).
[148] *Ibid.*, Art. 23 (3).

patent[149], unless the licensees, or the proprietor of the patent, have made, in good faith, effective and serious preparations to use the invention[150]. In such cases, the patent may continue in use provided that a non-exclusive licence is requested[151].

Chapter II of the CPC provides rules regarding the proprietor's rights over his patented invention. It is established that he has the right to prevent all third parties, without his consent, from making, offering, putting on the market, using, importing or stocking a product or the process which is the subject matter of the patent within the territory of the Community[152]. Moreover, the proprietor has also the right to prevent all third parties, without his consent, from supplying or offering to supply the patented invention to third parties who are not entitled to exploit the patented product within the Community[153]. On the other hand, there are some limitations to these rights, which in this case does not constitute an infringement of a Community patent, in so far as the acts upon this invention are done, *inter alia*, privately and for non-commercial purposes, for experimental purposes, and for extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with medical prescription[154].

The CPC also contains rules for the translation of the claims in examination or opposition proceedings[155], as well as the legal status of the translations[156], and rules for the translation of the specification of the Community patent[157].

Moreover, it is provided that when a Community patent - as a result of a European patent application in which a Contracting State of the CPC is designated - is revoked, the

---

[149] *Ibid.*, Art. 24 (1).
[150] *Ibid.*, Art. 24 (3).
[151] *Ibid.*, Art. 24 (2).
[152] *Ibid.*, Art. 25.
[153] *Ibid.*, Art. 26.
[154] *Ibid.*, Art. 27.
[155] *Ibid.*, Art. 29.
[156] *Ibid.*, Art. 31.

effects of that patent, as provided by Chapter II of the CPC, will not apply[158]. Additionally, the effects of a Community patent are governed by the provisions of the CPC and the infringements of a Community patent will be governed by the national law relating to infringement of a patent, in accordance with the provisions of the Protocol on Litigation[159].

It is also established that if the subject-matter of a Community patent is a process for obtaining a new product, the same product when produced by another party shall be considered as a result of the patented process, in absence of proof to the contrary.[160]

Further, Articles 36 and 37 of the CPC provide that a prior patent application or a prior national patent shall enjoy the benefit of the same prior right effect with regard to a Community patent as a European patent application does in a Contracting State which has been designated.[161] This follows the understanding that, if a national patent application was not published, for reasons of secrecy, and enjoys a prior right effect with regard to a national patent in that State having a later date of filing, the same shall apply to a Community patent[162]. Further, if a national patent was granted based on a prior use of an invention or based on a right of personal possession of that invention, the same rights in respect of a Community patent shall apply for the same invention[163]. The rights to a Community patent shall not be extended to acts concerning a product covered by the patented invention which are done within the territory of a specific Contracting State, if the owner of that patent has put it on the market in that State. This rule will apply only if

---

[157] *Ibid.*, Art. 30. *Cf.* Rules 6, 7 and 8 of the Implementing Regulation of the CPC.
[158] *Ibid.*, Art. 33.
[159] *Ibid.*, Art. 34.
[160] *Ibid.*, Art. 35.
[161] *Ibid.*, Art. 36 (1).
[162] *Ibid.*, Art. 36 (2).
[163] *Ibid.*, Art. 37 (1).

the national patent law of that State makes provision to the same effect in respect of national patents[164, 165].

The CPC, when establishing the provisions dealing with a Community patent as an object of property, establishes firstly that a Community patent shall be dealt with in the context of the whole of the territories of the Community and in its entirety, as a national patent of the Contracting State[166], provided that the applicant, or his representative, has its residence or place of business within the territory of one of the Contracting States and, in the case of a joint application, if one of the applicants would meet one of these requirements[167]. It is also provided that if proceedings relating to judgments or other official acts being enforced against Community patents, the national courts or other authorities of that Contracting State shall have exclusive jurisdiction in respect of it.

Furthermore, the Community patent may be transferred[168], licensed[169] or offered to any person who would like to license it with the payment of appropriate compensation for the licensee (licences of right)[170] and, as a matter of fact, all European patent applications, in which a Contracting State of the CPC is designated, will be ruled by the wording of Articles 38 to 42 of the Community Patent Convention.

---

[164] *Ibid.*, Art. 37 (2).
[165] See, for further analysis of this matter, **John Neukon**, A Prior Use Right for the Community Patent Convention, [1990] 5 *EIPR* 165-169, and **John Neukon**, A Prior Use Right for the Community Patent Convention: An Update, [1991] 4 *EIPR* 139-141.
[166] CPC, Art. 38 (1).
[167] *Ibid.*, Art. 38 (3).
[168] *Ibid.*, Art. 39.
[169] *Ibid.*, Art. 42. A Community patent may be licensed in whole or in part for the whole or part of the territories in which it is effective and may be on an exclusive or non-exclusive basis.
[170] *Ibid.*, Art. 43. *Cf.* Rules 9 and 10 of the Implementing Regulations of the CPC.

5. SUBSTANTIVE PATENT LAW: ECONOMIC CLAUSES

With regard to the so-called "economic clauses"[171], it may be argued that they are one of the main reasons for the creation of a single unitary system for the protection of patents within the Community. As has been seen in Chapter 3, patents may be used as trade barriers between Member States of the Community and, as a consequence, may partition off national markets and threaten the principle of free movement of goods within the territories of the Community. The development of European case-law has been already analysed in relation with the principle of "exhaustion of patent rights[172]. It may even be argued that this provision of the CPC was mainly based on the development of the administrative and juridical jurisprudence of the Community. The granting of a compulsory licence may also be used as a trade barrier against products from other Member States of the Community. The CPC attempts to regulate the use of such a mechanism when employed by national authorities, based on national law. These two issues will be further described below.

5.1. Exhaustion of patent rights

The monopoly granted by the State to the inventor may, in some ways, be used against the establishment and functioning of the Common Market in so far as the proprietor of a patented product has the exclusive right to use the patented invention, which exercise may, in some cases, be against the principle of the free movement of goods. The proprietor of a patent has the exclusive right to manufacture and commercialise his invention and/or grant

[171]The economic clauses are probably so called because of the economic effects that they have in the context of an integrated system.
[172]See. *supra* .Chapter 3. Section 1.

licences to third parties. Although the proprietor of a patent, when exercising his rights over the patented product, is not automatically infringing the rules of the EC Treaty, he cannot use his patented invention against the objectives of the Community. The exercise of such a right has to be limited to fit in the Community interest.[173]

Article 28 of the CPC provides that:

> The rights conferred by a Community patent shall not extend to acts concerning a product covered by that patent which are done within the territories of the Contracting States after that product has been put on the market in one of these States by the proprietor of the patent or with his express consent, ...

The wording of Article 28 of the CPC is exactly the same as that provided by the first version of the Convention (CPC 1975). It is thus understood that, once the proprietor of a patent, or someone with his "express consent", has put the patented product on the market of any Contracting State, the rights upon that patent shall be considered exhausted to the extent that thereafter the patented product may circulate freely within the territories of the Community. The proprietor of that patent has no longer the right to prevent the circulation of that product. The same applies "... to rights conferred by a national patent in a Contracting State", as ruled by Article 76, CPC. The second part of Article 28 expressly states that the principle established will not apply if, under Community law, "...there are grounds which,..., would justify the extension to such acts of the rights conferred by the patent"[174].

Article 37 (2), CPC, states that the principle of exhaustion of rights will apply if - in the case of the proprietor of a national patent which has been granted based on prior use

---

[173]The development of the distinction between the existence and the exercise of IPRs has been described in Chapter 3, Section 1, Sub-section 1.1, *supra*. It seems that such a distinction is becoming of marginal importance within the context of the application of the IPRs within the Community. See, *e.g.*, references in note 16, Chapter 3, *supra*.

or personal possession of the invention, which enjoys the same rights in respect of a Community patent for the same invention - the national law of that State makes provisions to the same effect in respect of national patents.

5.2. Compulsory licences[175]

In relation to the granting of a compulsory licence by national law, it is provided by the CPC that the national provisions shall be applicable to Community patents. However, the effect of compulsory licences will face territorial limitation with regard to the Community. These effects will take place only in the territory of the State concerned.[176] Upon the granting of a compulsory licence in respect of a Community patent, the national authority shall communicate it to the EPO[177]. Also, each Contracting State shall provide for a final appeal to a court of law, "... at least in respect of compensation under a compulsory licence"[178].

Contracting States are not allowed to grant compulsory licences of a Community patent on the ground of lack or insufficiency of exploitation, if the patented product, though manufactured in this State, is put on the market in the territory of any other Contracting State, "... for which such a licence has been requested, in sufficient quantity to satisfy needs in the territory of that other Contracting State".[179]

---

[174]It is mainly related with the exception provided by Article 36 of the EC Treaty.

[175]For the purposes of the application of the provisions of the CPC, the term "compulsory licence" shall include "... official licences and any right to use patented inventions in the public interest" (CPC, Art. 45 (4)).

[176]CPC, Art. 45 (1).

[177]*Ibid.*, Art. 45 (3).

[178]*Ibid.*, Art. 45 (2). It is generally established by the CPC that "... in actions relating to compulsory licences in respect of a Community patent, the courts of the Contracting State the national law of which is applicable to the licence" shall have exclusive jurisdiction.

[179]*Ibid.*, Art. 46. The same applies in relation with a national patents (*Ibid.*, Art. 77). The CPC however provides that the Contracting States - for a period of ten years, with the possibility of extension of this period for another five years - may declare, when the depositing of its instrument of

It is also established that the principle of exhaustion of patent rights, established by Article 28 of the CPC, shall not apply either to Community patents[180] or to national patents[181], in relation with the granting of compulsory licences upon a patented product.[182]

6. THE SYSTEM OF JURISDICTION

Probably the main difference between the 1975 version of the CPC and that amended in 1989 by the Agreement, is that the latter creates a more complex system of jurisdiction. While the CPC 1975 established rules for the jurisdiction of national courts with the possibility of preliminary ruling by the European Court of Justice, with reference to the "Convention on Jurisdiction and Enforcement of Judgment in Civil and Commercial Matters", signed at Brussels on 27 September 1968[183], the amended version of the CPC goes further and adds, through the Protocol on Litigation[184], a system of jurisdiction by which one will find that national courts will act as Community patent courts of first and second instance[185], and a Common Appeal Court is established[186] with the task of ensuring uniform interpretation and application of the provisions relating to Community patents, "... to the extent to which th[o]se are not national provisions"[187].[188] Appendix III, below,

---

ratification, that it reserves the right to provide that Articles 46 and 77 will not apply within its territory to Community, European or national patents (*Ibid.*, Art. 83).

[180] *Ibid.*, Art. 45 (1), Last sentence.

[181] *Ibid.*, Art. 76 (3).

[182] See, generally, Chapter 3, Section 1, Sub-section 1.2, Paragraph 1.2.2, *supra*, for further information on the jurisprudence of the EC in relation with the granting of compulsory licences and its legal effects in the Community.

[183] OJ 1978 L304. Hereinafter the "Convention on Jurisdiction and Enforcement".

[184] OJ 1989 L401/34.

[185] Protocol, Art. 1.

[186] *Ibid.*, Art. 2.

[187] The Agreement, Art. 5.

[188] It is argued, nevertheless, that one of the main problems for the adoption of the CPC and the establishment of the COPAC has been the possibility of agreeing upon a single first instance jurisdiction, with uniform national procedural rules. See, *e.g.*, **Robin Lawrence**, Patent Litigation Reform - In Europe?, [1982] 2 *EIPR* 39-41, p. 40.

provides an outline, in diagrammatic form, of the system of jurisdiction that will be discussed in the present Section.

6.1. Jurisdiction under the CPC itself

Part VI of the CPC intends to provide general rules on jurisdiction and procedure in actions relating to Community patents other than those provided by the Protocol. It is thus established that, unless otherwise specified by the CPC or by the Protocol, the Convention on Jurisdiction and Enforcement shall apply to actions relating to Community patents[189].

As a basic rule the jurisdiction will be generally based on the defendant's domicile[190]. However, in patent infringement cases there are two other rules of the Convention on Jurisdiction and Enforcement which are relevant. Firstly, Article 5 (3) establishes that, in matters relating to tort, delict or quasi-delict, a person domiciled in a Contracting State may be sued in the courts of another Contracting State where the harmful event occurred. Secondly, Article 16 (4), Convention on Jurisdiction and Enforcement, determines that, in proceedings concerned with the registration or validity of patents, "... the courts of the Contracting State in which the deposit or registration has been applied for, has taken place or is under the terms of an international convention deemed to have taken place", shall have exclusive jurisdiction, regardless of domicile.

It is also established that national courts of the Contracting State (the national law of which is applicable to the licence) will have exclusive jurisdiction in actions relating to compulsory licences in respect of Community patents[191]. In actions relating to disputes between employer and employee, the national court of the Contracting State under whose law the right to a European patent is determined in accordance with Article 60 (1) EPC,

---

[189]CPC. Art. 66.

will have exclusive jurisdiction[192]. Accordingly, these national courts, when dealing with actions relating to a Community patent, shall treat the patent as valid [193].

In the case of actions relating to the subject-matter of a national patent granted in a Contracting State, it is also provided that the national courts referred to above will have jurisdiction with the limitation of its territorial scope[194], and that national authorities in actions relating to the right of a Community patent or to compulsory licences in respect of a Community patent will be understood within the meaning of "courts" as in the CPC and in the Convention on Jurisdiction and Enforcement[195]. Finally, it is established that national law relating to penal sanction for infringement shall be applicable in case of infringement of a Community patent[196].

6.2. Jurisdiction under the Protocol on Litigation

The Protocol on Litigation may be considered the cornerstone for the application and enforcement of the patent system which will be established by the CPC. The enforcement of patent rights in the courts is as important for harmonisation as the other subjects, such as substantive patent law. It was already argued, during the debates for and against the CPC, that infringement and validity of patent rights should be examined together in order to avoid discrepancies in the proceedings before different national courts[197].

For the purposes of the establishment of a system of jurisdiction and enforcement under the Protocol on Litigation, Contracting States must designate national courts, as

---

[190]Convention on Jurisdiction and Enforcement. Art. 2.
[191]CPC. Art. 67 (a).
[192]*Ibid.*. Art. 67 (b).
[193]*Ibid.*. Art. 72.
[194]*Ibid.*. Art. 68.
[195]*Ibid.*. Art. 70.
[196]*Ibid.*. Art. 74.

required by Article 1 of the Protocol on Litigation, for acting as Community patent courts of first and second instance, with the purpose of promoting specialisation in patent matters in certain courts of the Contracting States.[198] Also, a Common Appeal Court (COPAC) will be established, with legal personality[199] and enjoying extensive legal capacity accorded to legal persons under national law of the Contracting States. The COPAC shall have power to acquire or dispose of movable and immovable property and may also be party to legal proceedings[200]. The COPAC will sit in plenary session[201] and will have a registry[202]. An Administrative Committee with representatives of the Contracting States, the Commission of the European Communities and their alternate representatives will be established with, *inter alia*, the duty to determine the number of judges of the Common Appeal Court[203]. It is not yet decided where the COPAC will take place[204].

Again, the Convention on Jurisdiction and Enforcement shall apply to the provisions of the Protocol in so far as it is not specified otherwise. The Protocol itself, according to the Convention on Jurisdiction and Enforcement, expressly rules that jurisdiction shall be based on the defendant's domicile.[205]

Community patent courts whose jurisdiction is based on the Protocol[206] will have exclusive jurisdiction in respect of acts of infringement committed or threatened within the

---

[197] **J.L. Beton,** Future Prospects - Harmonisation of National Patent Laws, [January 1979] *EIPR* 13-19, at pp. 17-18.

[198] See the list of the courts designated by the Contracting States in the Annex to the Protocol, OJ 1989 L401/42.

[199] Protocol, Art. 3 (1).

[200] *Ibid.*, Art. 3 (2).

[201] It may, also, create chambers (Protocol, Art. 5 (2)).

[202] Protocol, Art. 5 (3).

[203] *Ibid.*, Art. 5 (1).

[204] *Ibid.*, Art. 2 (2).

[205] Protocol, Art. 14. *Cf.* Art. 2, Convention on Jurisdiction and Enforcement.

[206] Articles 14 (1) to (4) of the Protocol states that proceedings will be brought before the courts of the Contracting State where the defendant is domiciled, or has an establishment. If the defendant is neither domiciled nor has an establishment in one of the Contracting States, proceedings must take place in the courts where the plaintiff is domiciled or has an establishment. If neither the defendant

territory of any of the Contracting States, or actions in respect of the use made of the invention, as specified in Article 32 (1) of the CPC[207]. [208]

It is also worth mentioning that the Community patent courts whose jurisdiction is based on Article 14 (5) Protocol on Litigation - *i.e.*, the possibility of bringing the proceeding in the court of the Contracting State in which the act of infringement has been committed or threatened - shall have exclusive jurisdiction only in respect of acts committed or threatened within the territory of the State in which the court is situated.

6.2.1. First instance

At the first instance level, disputes will be solved either by the Revocation Divisions or by Community patent courts of first instance. The Revocation Divisions will have exclusive jurisdiction in relation to actions for limitation and revocation of Community patents, as provided by Chapters II and III, of Part III of the CPC.

Community patent courts of first instance are empowered to decide, exclusively, upon questions regarding all infringement actions, if permitted by national law, and all actions in respect of threatened infringements relating to Community patents[209]; in respect of actions for the declaration of non-infringement, if provided by national law[210]; in

---

nor the plaintiff fulfil these requirements, proceedings will take place in the courts where the COPAC has its seat.

[207] *Ibid.*, Art. 17 (1).

[208] For a more detailed analysis on the issues under the Convention on Jurisdiction and Enforcement related with intellectual property rights, see **Clare Tritton & Guy Tritton**, The Brussels Convention and Intellectual Property, [1987] 12 *EIPR* 349-354, **C.M. Wadlon**, Intellectual Property and the Judgment Convention, [1985] 10 *EL Rev.* 305-315. Also, for a broader analysis of the Convention see **A. McClellan**, The Convention of Brussels of September 27, 1968 on Jurisdiction, and the Recognition and Enforcement of Judgments in Civil and Commercial Matters, [1978] 15 *CML Rev.* 228-243, and **Hjalte Rasmussen**, A New Generation of Community Law? Reflections on the Handling by the Court of Justice of the Protocol of 1971 Relating to the Interpretation of the Brussels Convention on Jurisdiction and Enforcement of Judgments, [1978] 15 *CML Rev.* 249-282.

[209] Protocol, Art. 15 (1) (a).

[210] *Ibid.*, Art. 15 (1) (b). In this case the Community patent courts are not empowered to question the validity of a Community patent (*Ibid.*, Art. 15 (4)).

relation to all actions relating to the use made of inventions, by virtue of Article 32 (1) CPC[211]; and in relation to actions concerning counterclaims for revocation of Community patents[212]. With regards to a counterclaim for revocation, a Community patent court of first instance is empowered to order the revocation of the patent, to reject the application for revocation, or to maintain the patent in amended form[213]. A copy of the judgment of the Community patent court regarding a counterclaim for revocation will be sent to the EPO and, in the event of a judgment in favour of the maintenance of the patent in amended form, a copy of the text of the patent as amended shall also be sent to the EPO[214]. Finally, a final judgment revoking or amending a Community patent will have effect in all Contracting States, as specified by Article 33 CPC[215].

With regards to an European patent application which depends on a decision related to the patentability of the invention, it is also important to note that any judgment before a Community patent court of first instance will be given only after the EPO has granted a Community patent or refused an European patent application.[216]

6.2.2. Second instance

In the second instance, disputes relating to Community patents will be dealt with before the Community patent courts of second instance and before the Common Appeal Court.

The Community patent courts of second instance will decide on appeals which come from the courts of first instance in respect of proceedings in which the latter courts

---

[211] *Ibid.*, Art. 15 (1) (c).
[212] *Ibid.*, Art. 15 (1) (d). The court in question will treat the Community patent as valid, unless its validity has been challenged by the defendant (*Ibid.*, Art. 15 (2)) and, the Community patent court, in with which a counterclaim for revocation of a Community patent has been filed, has to communicate the EPO of the date of filing the counterclaim for revocation (*Ibid.*, Art. 16).
[213] *Ibid.*, Art. 19 (1) (a), (b) and (c), respectively.
[214] *Ibid.*, Art. 19 (2) and (3), respectively.
[215] *Ibid.*, Art. 20.

have exclusive jurisdiction[217]. An appeal may be lodged in accordance with the national law of the Contracting State where the court is located[218]. When an appeal before a second instance court raises issues within the jurisdiction of the COPAC, the Community patent court shall stay its proceedings and refer them to the COPAC for a judgment[219]. In this case the Community patent court of second instance may give a final judgment only after the ruling of the COPAC[220].

The COPAC will have exclusive jurisdiction, acting as a second instance court, hearing appeals from the Revocation and Administrative Divisions of the EPO[221], as well as on issues concerning infringement and validity of Community patents arising in appeals from first instance courts[222]. The Common Appeal Court will give rulings on fact and law[223] and shall use the provisions of the Agreement as the applicable law[224].The judgements of the COPAC will be binding in further proceedings of the case[225].

---

[216] *Ibid.*, Art. 18.
[217] *Ibid.*, Art. 21 (1).
[218] *Ibid.*, Art. 21 (2).
[219] *Ibid.*, Art. 23 (1).
[220] *Ibid.*, Art. 23 (3). The court of second instance is allowed to continue its proceedings if there is no possibility of a judgement of the Common Appeal Court being prejudged (*Ibid.*, Art. 23 (2)).
[221] *Ibid.*, Art. 28. The procedure relating to appeals from the Revocation and Administrative Divisions is regulated by Article 61 (2) of the CPC, which refers to the application of Articles 106 to 109 of the EPC. It is then argued that the jurisprudence of the Boards of Appeal, in relation with the Articles of the EPC above mentioned, will be generally applicable to such appeals (**Gerald Paterson**, note 9, *supra*, p. 493).
[222] *Ibid.*, Art. 22.
[223] *Ibid.*, Art. 24.
[224] *Ibid.*, Art. 26.
[225] *Ibid.*, Art. 27.

6.2.3. Third Instance and preliminary ruling

The COPAC will have jurisdiction in appeals from Community patent courts of second instance, in respect of the issues provided by Article 22 of the Protocol, only if it is permitted by national law[226].

According to Article 5 of the CPC, the Common Appeal Court is empowered to give preliminary rulings relating to the interpretation of the Agreement, in respect of matters not falling within its exclusive jurisdiction, and in relation to the validity and interpretation of the provisions enacted in implementing the Agreement[227]. Community patent courts of first and second instance may also raise questions for the COPAC if they consider that such a ruling is necessary to enable them to give a judgment.

The COPAC, on the other hand, may raise questions to the European Court of Justice, requesting a preliminary ruling in accordance with Article 177 EC Treaty, in connection with any provisions of the Agreement which, from its interpretation, may be in conflict with the EC Treaty[228]. Also, national courts may request a preliminary ruling from the European Court of Justice in connection with the interpretation of the provisions on jurisdiction applicable to actions relating to Community patents[229].

CONCLUSION

Chapter 3, above, described the Community laws and practices towards the harmonisation of national regulations dealing with the protection of patents. The examination carried out by Chapter 3 has focused primarily on the effects of the

---

[226] *Ibid.*, Art. 29.
[227] *Ibid.*, Art. 30 (1).
[228] The Agreement, Art. 2.

exercise of patent rights within the territory of the EC, as a means of ensuring that such exercise does not put into risk the process of trade liberalisation in the Community. It has also described the legislative, administrative and juridical approach of the EC in this regard. In its Conclusion, Chapter 3 observed the important role that the institutional structure of the EC has played for the establishment of a common understanding on the exercise of patent rights within the territory of the Community. In general terms, the conclusive remarks of Chapter 3 has also drawn up some comparisons with the institutional mechanisms provided by the MERCOSUL for the harmonisation of national laws and regulations, as well as for the co-ordination of the juridical understanding of the issues arising from the disputes on patent rights.

The present Chapter described the attempt of the EC to establish a common system of jurisdiction, enforcement and standards of substantive patent law, which was designed to play a crucial role towards the harmonisation of national laws, regulations and practices in the field of patent protection, hence contributing to the establishment and operation of the integrating project. A complex system was built up in which two different but complementary institutional mechanisms (the EPC and the CPC) would work in harmony to guarantee that patent rights and its exercise would be harmonised throughout the Community and beyond. The EPC system, as mentioned above, has been working efficiently for nearly twenty years and may provide some guidance for future projects on procedural harmonisation of patent rights. On the other hand, the CPC framework has never come into force, although a comprehensive system of jurisdiction, enforcement and substantive law was carefully designed by the Member States to unify patent protection on a broad basis. Though

---

[229] *Ibid.*, Art. 3.

the experience of the EPC and the failure to implement a common system for the EC are different in substance - as far as the latter is designed to be a unitary and autonomous system with jurisdiction throughout the territory of the EC and the former is a complementary system to national patent frameworks, with no direct relation with an integrating process, consisting in a bundle of rights - both examples are of relevance for the discussion of the harmonisation of patent rights within the context of the MERCOSUL.

In the negotiations of the MERCOSUL, a common existing argument is that a complex and detailed set of rules are not necessarily a point in favour of harmonisation of patent laws, but rather against the practical implementation of common measures within an integrated area. This argument seems to take account of one side of the discussion only, in so far as there is a need to unify in a minimum basis substantive patent law principles and concepts, but there is also a need of some degree of harmonisation of administrative and juridical understanding of the granting of patent rights and of the control of the exercise of these rights. Some institutional and legislative mechanisms, within the integrated area of the MERCOSUL, are necessary in the short term.

Taking that into account, it is possible to affirm that the integrating project of the MERCOSUL requires more detailed norms on substantive patent law and on the control of its exercise, than those what have been agreed so far by the negotiators. In the following two Chapters, the MERCOSUL's attempt to unify patent rights will be described in more detail and further conclusive remarks will be made. Yet it is apparent that a common administrative structure is necessary to deal with patent rights inside the integrated area of the MERCOSUL. The MERCOSUL will face the

problems of different administrative procedures being applied by national patent offices. If it is not possible to establish an ambitious system of patent granting procedures under a common institutional framework, the negotiations in the MERCOSUL should consider at least the establishment of an organ which would give preliminary rulings on patent granting procedures, eventually working also as an instance of administrative appeal, or both. This seems to be a feasible solution for harmonising the way national patent offices will deal with the granting of patents. On the other hand, this suggestion could lead to further delays in patent granting procedures, thus making patents more difficult to obtain and more costly.

In order to have a common structure judging appeals or giving preliminary rulings from national patent offices, a detailed legal structure has to exist. Without harmonised rules for patent protection, the establishment of any further organs is not practical. The MERCOSUL will have to find out how to address several issues connected to patents and its exercise and must do so in the most comprehensive way possible. It is necessary to address complex and controversial issues, such as the protection for pharmaceuticals, biotechnology and plant varieties, as well as regulations on the free movement of goods and competition within the integrated area. As has been seen throughout Chapters 3 and 4, the mechanisms used to make all these issues equivalent are very complex and have required different forms of harmonisation mechanisms. Thus, the negotiating process of the MERCOSUL must determine which are the appropriate mechanisms to harmonise several fields of patent rights, and how they will be applied. The mechanism of inter-State Convention should be carefully considered, despite the unsuccessful example of the CPC.

It is also necessary to emphasise that disputes with regional territorial scope will certainly take place in the context of the MERCOSUL, and that national courts must have a co-ordinated understanding of the issues arising from these disputes. The analysis of Chapters 3 and 4 seems to emphasise the need of a common juridical structure for the MERCOSUL which will co-ordinate the juridical actions of national courts. This appears to be vital for the proper establishment of the Common Market and for its smooth operation. This will nevertheless be facilitated only after all instances of discussion are exhausted, *i.e.* the proper harmonisation of substantive aspects of patent law and a common and co-ordinated approach towards patent granting procedures.

Finally, it is worth recalling what has been said in the general Introduction of the thesis, that the present research has attempted to describe in more detail the European experience to arrive to general conclusions for the integration project of the MERCOSUL. The discussion which took place in the present Chapter, about the experience to set up a common system of substantive patent law and jurisdiction in Europe, only aims to provide the MERCOSUL with a view of a possible solution towards patent harmonisation.

CHAPTER 5
SUBSTANTIVE PATENT LAW: PATENTABILITY

INTRODUCTION

This Chapter analyses aspects of patent protection as a means of making a contribution to the integration process of the MERCOSUL. It is not intended to impose principles or define complex issues in the industrial property international discussion. States Parties of the MERCOSUL will nevertheless be obliged to comply with the provisions included in their international commitments. This Chapter thus utilises, as a legal basis, agreements, laws and regulations on three levels: international, national and supranational.

The international level is based on the TRIPS Agreement[1] and the treaties and provisions administered by the WIPO[2], particularly the Paris Convention. The latter does not deal, in detail, with the points which will be discussed below. On the one hand, the Paris Convention is designed to set up general principles of intellectual property law, requiring "...Member Countries to observe certain minimum standards of protection, but their [the Paris and the Berne[3] Conventions] main prescription is that each Member Country should provide national treatment to nationals of other Member Countries"[4]. The Paris Convention is not intended to impose a detailed legal

---

[1] *Cf.* Chapter 2, Section 2, Sub-section 2.3, *supra*.
[2] *Cf.* Chapter 2, Section 1, *supra*.
[3] *Cf.* note 9, Chapter 2, *supra*.
[4] **Rajan Dhanjee & Laurence Boisson de Chazournes**, Trade Related Aspects of Intellectual Property Rights (TRIPS): Objectives, Approaches and Basic Principles of the GATT and of Intellectual Property Conventions, [1990] 5 *JWT* 5-15, at p. 6.

framework and leaves discretion to the national laws over defining patentable subject-matter and setting up rules governing enforcement of industrial property rights.[5]

On the other hand, although the former GATT system dealt only marginally with intellectual property issues, it accepted that they might become barriers to international commerce[6]. The evolution of the international trade system and the consequent conclusion of the Uruguay Round of negotiations in 1994 sets up a new legal framework that, more detailed than the Paris Convention, proposes minimum standards of intellectual property protection which shall be implemented by the national laws of the Members of the WTO. Members, therefore, must comply with the standards provided by the TRIPS Agreement within a specified period of time.[7] It was not within the mandate of the Uruguay Round to impose a strict system of intellectual property law. Neither the Paris Convention nor the TRIPS Agreement are designed to create procedures, interpret provisions or make definitions. Both are intended to be a general framework to harmonise national intellectual property laws, although the TRIPS Agreement is a more detailed text. Current developments in the Paris Union must also be taken into consideration. The Paris Union has been the founder and the encouragement for the establishment of an international system of industrial property law. It is probable that the foreseen conclusion of the negotiations of the PLT[8], will complement the trade-related aspects of intellectual property rights.

---

[5]The Paris Convention is essentially based on the principles of "national treatment" and the "right of priority". See, generally, Chapter 2, Section 1, Sub-section 1.1, Paragraph 1.1.2, *supra*, for further analysis of these principles.

[6]There are several provisions of GATT that regulate intellectual property matters in relation to multilateral trade. See, *e.g.*, GATT Doc. N. MTN.GNG/NG11/W/6 (22 May 1987) GATT Provisions Bearing on Trade-Related Aspects of Intellectual Property Rights, Note by the Secretariat, and Chapter 2, Section 2, Sub-section 2.1, *supra*.

[7]*Cf.* Chapter 2, Section 2, Sub-section 2.3, *supra*.

[8]"Patent Law Treaty". See, for a complementary view on the negotiations of the PLT, Chapter 2, Section 1, Sub-section 1.4, *supra*.

At the national level, only Brazilian legislation will be taken into consideration[9]. It will be analysed primarily in terms of the issues as in Law N. 5.772, of 21 December 1971[10]. Further, the present Chapter discusses the developments on the Parliamentary negotiations of PL N. 824/91[11], which eventually became law on 15 May 1996[12].

The analysis on the regional level utilises the negotiating process of the MERCOSUL, paying particular attention to the work carried out by Sub-group N. 7, on Industrial and Technological Policy[13], more specifically the negotiations within the Committee on Intellectual Property[14]. As a result of the negotiations carried out by

---

[9]It was decided that only Brazilian legislation would be analysed in detail. There is no technical reason for this. It is a decision based on practical and personal grounds.

[10]As published in **INPI** (organisation by Denis Borges Barbosa), Legislação da Propriedade Industrial e do Comércio de Tecnologia, Rio de Janeiro: Companhia Editora Forense (1982), and known as the Industrial Property Code. Hereinafter the "CPI".

[11]PL is the abbreviation of "Projeto de Lei", or legislative "Bill, in English. PL N. 824/91, which aims to regulate duties and rights related to industrial property, was submitted to the Brazilian National Congress, by President Fernando Collor, on 30 April 1991 (Mensagem Presidencial N. 192/91). It was discussed and amended by the Chamber of Deputies (Low Chamber), being further considered by the Federal Senate (High Chamber), under the number PLC N. 115/93. The text approved in the Federal Senate was sent back to the Chamber Deputies which decided upon only the proposed provisions amended by the Federal Senate.

[12]Law N. 9.279, of 14 May 1996 (hereinafter the "Law 9279/96"). Published in *Diário Oficial* (the Brazilian Official Journal), 15 May 1996, Seção 1, pp. 8353-8366. It is worth noting that, by virtue of Article 244 of the Law 9279/96, the CPI is revoked. It is also necessary to mention that Law 9279/96 will come into force only after one year counting from the date of publication. Law 9279/96 has, nevertheless, come into force on 15 May 1996 for the purposes of "pipeline protection" (discussed further in Part 2, Section 1, Sub-Section 1.2, *supra*), and for the protection of pharmaceutical and chemical products and processes and foodstuff. It has been decided that the present research would also consider the CPI in detail, because it is the main legal framework for patent protection which has been in force in Brazil for twenty five years and which will be almost entirely valid until 14 May 1997. In one way or another, the CPI has determined the evolution of the Brazilian patent system, by clarifying the distinction between "old" patent norms (the CPI) and "modern" patent protection rules (Law 9279/96). And the latter follows the trend determined by the TRIPS Agreement.

[13]The Treaty of Asuncion, in its Annex V, created various Sub-groups designed to co-ordinate macro-economics and sectoral policies. Sub-group N. 7, on Industrial and Technological Policy, is the one which has considered the unification of national intellectual property laws. See, for further information on the institutional establishment of the MERCOSUL, Chapter 1, Section 2, *supra*.

[14]Resolution of the Common Market Group MERCOSUL/GMC/RES. N. 25/92 (published in [1992] 7 *BILA* 37) decides upon the creation of the Committee on Intellectual Property, as part of Sub-group N. 7, empowered to analyse, negotiate, and propose a common text on the harmonisation of industrial property laws and policies between the States Parties of the MERCOSUL.

the Committee on Intellectual Property, there are two instruments which will be used: firstly, the "Propuesta de Disposiciones Legales en Material de Invenciones y Diseños Industriales de Armonizacion Prioritaria"[15], which is the first written proposal of a text aiming to harmonise national laws in the MERCOSUL; secondly, the "Proposta Brasileira de Acordo Visando à Harmonização de Leis em Matéria de Propriedade Industrial entre os Países Integrantes do Mercosul"[16], which is a document prepared by the Brazilian government that aims to suggest changes to a draft text agreed among the States Parties of the MERCOSUL.

This Chapter is, for practical purposes, divided into two parts. Part 1 discusses the basic conditions for the granting of a patent; exclusions and exceptions from patentable subject-matter; rights conferred by a patent; and the term of protection. Part 2 studies the issues about the protection of pharmaceutical products and processes, biotechnology and plant varieties.

PART 1: GENERAL AND INTRODUCTORY ISSUES

An invention is a result of the intellectual labour of the inventor. "Inventive activity" as such is always prior to the result which will be finally called an invention. This activity, thus, is something personal, immaterial and belonging to the inventor[17]. The

[15]Document prepared by the International Bureau of the WIPO, on request of the Committee on Intellectual Property of the MERCOSUL (Geneva: WIPO (May/1994)). Hereinafter the "WIPO Proposal".

[16]Hereinafter the "Brazilian Proposal". Not published.

[17]**Douglas Gabriel Domingues**. Direito Industrial - Patentes , Rio de Janeiro: Companhia Editora Forense (1980), p. 29. There is material property (*res quae tangi possunt*) and intangible property (*res quae tangi non possunt, quae in jure consistunt*). The latter is the one which includes the concept of intellectual property.

subject-matter of a patent is, therefore, the right conferred upon this final result: the invention[18].[19]

To analyse the general concept of a patent two aspects may be considered: a technical and a legal aspect. The first is the technical analysis of the activity which leads to the invention. The second aspect is related to the patentability of a product or process, which, legally speaking, includes the technical aspects which have been referred to.[20] The technical and the legal aspects are very much related and will be taken into consideration in the administrative[21] or in the juridical level.

Several basic aspects of a patent must be analysed in the first place. Initially, the patent applicant must meet the requirements of novelty, non-obviousness and usefulness. Then, the general exclusions and exceptions of patent laws will be further

---

[18]The rights included in the concept of IPRs protection may be defined on two levels: nationally and internationally. At the national level, the essential legal source is the constitutional principle of a "right of a property". Then, the requirements and rights provided by national secondary law. In the international level, the multilateral negotiations refers to "general principles of intellectual property law" and "trade-related aspects of intellectual property rights". The former is normally included in the international arrangements administered by the WIPO, while the latter is generally related with IPRs within the context of a trading environment, *i.e.* the WTO system and regional integration arrangements.

[19]The concept of an invention, as such, is beyond the scope of this work. This Chapter does not intend to go deeper into this discussion in so far as most of the instruments which will be analysed *infra* have not tried to do so. Note, however, that the WIPO Proposal states in Article 1 (1) that "[i]t is understood as an invention an idea which is applicable in practice to the solution of a specific technical problem. An invention may refer to a product or a process". This Chapter analyses only the legal aspects of the concept. It is worth mentioning, however, that the concept of an invention is commonly mixed-up with the concept of discovery. In a legal sense, discoveries are not protected under patent law. An invention, in general, may be protected in three ways: when it is a product and when it is a process to obtain a product or an industrial result. See, for further discussion, **João da Gama Cerqueira**, Tratado da Propriedade Industrial, Rio de Janeiro: Revista Forense (1952), V. 2, Tomo I, pp. 53-67.

[20]**João da Gama Cerqueira**, Tratado da Propriedade Industrial, Rio de Janeiro: Revista Forense (1946), V. 1, at p. 229. Gama Cerqueira goes further and states that "[o]nly the patentable invention is necessarily within the scope of the law, thereupon varying in accordance with the laws of different countries. The technical concept of an invention may also vary, in accordance with the state of the art and the progress of industry. Thus, what is considered an invention today, might be interpreted in the future simply as innovation without importance".

[21]In Brazil the administrative body established to analyse and grant patent for inventions, as well as deciding upon administrative appeals, is the National Institute of Industrial Property (INPI), created by Law N. 5648, of 11 December 1970, as amended by Law 9279/96, Article 240.

analysed. In the second place, there are rights conferred against the patent, where an exception is provided by most industrial property laws, *i.e.* the mechanism of a compulsory licence. Finally, the length of time provided for the use of the rights conferred thereby, is also within the introductory aspects of this Chapter.

1. BASIC CONDITIONS

When there is an application for a patent, three basic requirements must be met: the invention has to be new (novelty), has to involve an inventive step (inventiveness or non-obviousness) and has to be capable of industrial application (usefulness). The patent will not be granted if the applicant fails to meet any of these legal requirements. These basic conditions of patentability are generally of wide acceptance by both developed and developing countries' national legislation.

1.1. Novelty

The novelty requirement for the patentability of an invention is commonly included in the laws of various countries as a condition *sine qua non* for the granting of a privilege to the inventor. In many cases, there is an invention which is new for the inventor, but is not sufficiently novel to meet the legal requirements. Commonly, an invention will be deemed new when not included in the "state of the art". Hereupon, the "state of the art" shall be understood, generally, as comprising everything which has been made available to the public.

Current Brazilian legislation seems to follow a similar approach to that provided by the EPC[22]. The CPI requires novelty as one of the conditions for the patentability of an invention and Article 6 (1) further says that an invention will be considered new when not within the state of the art.[23] In addition, Article 6 (2), CPI, defines the state of the art "... as including everything which has been made available to the public before the filing date, by means of written or oral description, by use or by any other means". The concept of the state of the art includes the disclosure of an invention within Brazil or in a foreign place.[24] AN 17/76, moreover, aiming to regulate the general concepts provided by the CPI, says that it is included in the state of the art "... everything, in any field of activity, which has been put into the reach of the public, anywhere in the world, by any means of communication and/or by use, before the filing date, ...".[25]

Such concept of "state of the art" has been controversial during the negotiations of the PLT. Where the text of Article 11 (2) (c), PLT, proposes that Contracting Parties shall be free to exclude from the prior art disclosures which have occurred in a foreign place, it must be understood that Contracting Parties may opt either for the absolute or the local novelty system. In addition to the basic proposal, the US suggested, by means of "... a permitted interpretation or clarification of the

---

[22]*Cf.* Chapter 4, Section 3, Sub-Section 3.1, *supra*.

[23]See, also, Ato Normativo INPI N. 17, of 11 May 1976, published in **INPI**, note 10, *supra*, Item 1.1.2. Hereinafter the "AN 17/76".

[24]Therefore providing the concept of "absolute" or "universal" novelty. The Brazilian position has been traditionally on the application of the absolute concept. See, *e.g.* statement by the representative of Brazil in the negotiations of the PLT strongly supporting "the notion of absolute novelty." (PLT I Conf. Rec., para. 840, at p. 341). Further, Law 9279/96, in Art. 11 (1), proposes the continuation of the absolute novelty system in Brazil.

[25]AN 17/76, in Item 15.5 (e), further says that what is included in the state of the art shall be considered "in the public domain". Therefore, everything included in the state of the art, by means of interpretation of Brazilian legislation, shall be considered in the public domain and, as a consequence, not patentable (AN 17/76, Item 15.5.1).

meaning of the notion of 'made available to the public'"[26], that Contracting Parties "... shall be free to exclude from the prior art matter which is not identified and organized in a manner that makes the matter accessible to the public"[27]. The US said that such limitation should be provided in so far as, for example, a written document which has been placed on a library shelf, but has not been indexed or in some ways made retrievable, shall not be included in the state of the art in so far as it is not possible to define accurately its availability to the public.[28] In contrast, with reference to the example given by the US[29], the EPO has stated that:

> ..., where the written description is in the form of a patent specification or any other document, the content of the document is admissible prior art if the document was in a place to which members of the public has access. Thus a document which is proved to have been on the shelves of a public library is admissible prior art, regardless of whether any person looked at it.[30]

Several countries[31] opposed the inclusion of the possibility of the local novelty concept within the PLT negotiations. As coherently suggested by the representative of the United Kingdom, legislation should not propose such a limitation. The interpretation of "...the scope and meaning of the notion of availability..." should be left to the national courts[32].

The TRIPS Agreement, on the other hand, is vague when discussing the subject and has not suggested any detailed definition of the novelty concept. The

---

[26]As interpreted by the German representative, in para. 834.2, PLT I Conf. Rec., p. 342.
[27]PLT/DC/50, of 10 June 1991, as published in PLT I Conf. Rec., p. 151.
[28]See paras. 833.2 and 896, PLT I Conf. Rec., at pp. 340 and 347, respectively.
[29]In paras. 833.2 and 896, PLT I Conf. Rec., pp. 340 and 347.
[30]**Gerald Paterson**, The European Patent System: The Law and Practice of the European Patent Convention, Oxford: Sweet & Maxwell (1992), para. 9-12, at p. 375. See, also, Decision T381/87 (RESEARCH CORPORATION/Publication), [1989] EPOR 138.

provisions of the TRIPS Agreement clearly accept both principles, *i.e.* the absolute and relative novelty concepts. It is thus possible to understand that, as a consequence of the approval of the PLT as a complementary multilateral agreement on patents, Members of the WTO Agreement will use the Paris Union's bias to exclude the application of the local novelty concept in a world-wide basis.

As has been analysed above, the wording of the law is generally strict. Once the disclosure of an invention occurs, such an invention lacks novelty and is therefore not capable of legal protection. Nevertheless, some exceptions apply to the novelty concept. In the wording of the Paris Convention there are (1) the "right of priority" principle and (2) disclosures which will not affect the novelty of an invention within a specified period of time (the "grace period").

With regard to the right of priority, the Paris Convention establishes that "[a]ny person who has duly filed an application for a patent,..., shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed"[33]. The "right of priority" principle is thus an exception to the novelty requirement. The principle accepts that the disclosure of a patentable invention, for the purposes of filing an application in another country of the Paris Union, within a period of one year prior to the application will not be considered as included in the state of the art.

Accordingly, Article 87 of the EPC, Articles 7 and 8 of the CPI and Articles 16 and 17 of Law 9279/96, establish that an applicant who has filed an application for

---

[31]Including Argentina, Brazil, Germany, the Soviet Union, the United Kingdom and Uruguay. See, generally, for these opinions and others, paras. 830 to 932, pp. 339-352, PLT I Conf. Rec..
[32]PLT I Conf. Rec., para. 907, p. 349.

a patent in any Contracting Party to the Paris Union (or related bilateral agreements) shall enjoy a right of priority during a period of one year from the date of filing of the first application.[34]

The Paris Convention goes further and, considering an improvement to the novelty principle, accepts that some other type of disclosures, which are not for the purpose of filing an application, shall be considered by national legislation, according to the period for priority. This includes, for instance, the introduction of goods into exhibitions[35]. Art 11 (1), Paris Convention, says that Members of the Paris Union shall grant temporary protection to patentable inventions, in respect of goods exhibited at official or officially recognised international exhibitions held in the territory of any of the member State of the Paris Union.[36]

In the EPC, for instance, the disclosure of an invention which has happened six months before the filing of an European patent application, and if it was due or in consequence of an abuse in relation to the applicant or to his legal predecessor, or the fact that the disclosure of the invention has taken place at an official, or officially recognised, international exhibition, will not prejudice the novelty of such invention[37]. In the latter case, however, the applicant must communicate that the invention has been disclosed in such an official, or officially recognised, exhibition when filing the

---

[33]Paris Convention, Art. 4 (C) establishes that such a period shall be for twelve months for patents. See, for further discussion on the "right of priority" principle, Chapter 2, Section 1, Sub-section 1.1, Paragraph 1.1.2, *supra*.

[34]The PLT does not refer to the right of priority directly. Article 7 proposes rules governing the rights of an applicant who wishes to enjoy a priority but, for whatever reason, has not claimed the priority. In such case it is suggested by Article 7 (1), that the applicant "...shall have the right to claim such priority in a separate declaration submitted to the Office within a period to be fixed by the Contracting Party which shall be at least two months from the filing date of the subsequent application and not more than four months from the date on which the period of twelve months from the filing date of the earlier application expired". *Cf.* Law 9279/96, Art. 16 (1), (3) and (6).

[35]Paris Convention, Art. 11 (2).

[36]See, generally, Paris Convention, Art. 11.

application.[38] Moreover, within four months of the filing of the European application, the applicant shall file a supporting certificate, issued at the exhibition by the authority responsible for industrial property protection, stating that the invention was exhibited there and certifying that the invention was displayed during the exhibition. This certificate must also be accompanied by an identification of the invention. [39]

In Brazil, the CPI said, in Article 7, that before filing an application, the author is entitled to priority, if he wishes to "...make a demonstration, a scientific communication or a official, or officially recognised, exhibition". Article 12 of the Law 9279/96, on the other hand, lists some disclosures which will not be considered within the state of the art. Such provision is quite similar to the proposed text of the PLT. In fact, as stressed during the negotiations on the PLT, the "grace period" is a consequence of the "first-to-file" system.[40]

Law 9279/96, for example, considers an exception to the concept of novelty, just as stated by Article 11 of the Paris Convention (*i.e.* official exhibition). Law 9279/96 provides that an invention will not be included in the state of the art if it was done twelve months before the filing date or the priority of the patent, by the inventor[41]; by the INPI using official publication, without the consent of the inventor,

---

[37]EPC, Art. 55 (1) (a) and (b).
[38]*Ibid.* Art. 55 (2).
[39]*Ibid.* Art. 55 (2) and Rule 23, Implementing Regulations EPC.
[40]See, *e.g.*, PLT I Conf. Rec., paras. 934, 935 and 956, where a clearer link is drafted between the "grace period" and the "first-to-file" concept. These discussions have taken place in so far as the US has emphatically proposed, within the context of the novelty concept, that "[a]ny Contracting Party that awards patents to the first-to-invent shall be free to also consider as prior art an invention which was made before the invention claimed in an application ..." (PLT/DC/6, 1 March 1991, as published in the PLT I Conf. Rec., p. 122). Such a proposal has been controversial and may become one of the most difficult obstacles barring the conclusion of the PLT. The "first-to-invent" system is recognised only by the US and the Philippines, in so far as the new Canadian patent law provides for the "first-to-file" system. See, for more detailed discussions on Art. 11, PLT, paras. 830.3 to 932, PLT I Conf. Rec..
[41]Law 9279/96, Art. 12, (I).

and based on information obtained from the inventor or from his acts[42]; or by third parties based on information provided directly or indirectly by the inventor or by acts of the latter[43].[44]

In the territory of the MERCOSUL, national laws require universal novelty as a condition for the patentability of an invention[45], as also suggested by the WIPO Proposal[46]. The Brazilian Proposal, on the other hand, requires only that States Parties shall grant patents to inventions which are new. It seems that the MERCOSUL negotiators have considered that national laws have already contemplated the principle of "absolute novelty" and that further discussion about this matter was not necessary in the text of a common agreement on patents for the MERCOSUL. In addition, all States Parties of the MERCOSUL are Contracting Parties to the Paris Convention and must comply with the requirements of the "right of priority" principle.

Some other exceptions to the principle of novelty, as well as further expansions of the understanding of the right of priority principle, have been considered in current negotiations within the Brazilian Parliament. Further analysis on the issues of "pipeline protection" are further discussed in this Chapter, Section 1, Part 2, *infra*.

---

[42]*Ibid.*, Art. 12, (II).
[43]*Ibid.*, Art. 12, (III).
[44]Law 9279/96 provides for exceptions to the novelty concept, particularly the so-called "grace period". Note, in addition, that Article 12, PLT, which proposes for the establishment of the "grace period", in an international basis, has raised some controversy. See, for more discussion on the subject, PLT I Conf. Rec., pp. 352-354, paras. 933-964.
[45]See **Ministério das Relações Exteriores (MRE)**, Quadro Demonstrativo de Patentes: MERCOSUL (1993), p. 8.
[46]WIPO Proposal, Arts. 3 and 5.

To conclude, it is important to say that neither the TRIPS Agreement nor the Brazilian Proposal provide any detailed understanding of the novelty requirement. Further, in relation with the "right of priority" principle, as established by the Paris Convention, the Brazilian Proposal makes no reference to the subject. It is necessary to say, nevertheless, that all States Parties of the MERCOSUL are Members of the WTO Agreement[47] and of the Paris Union. Both require that Members shall comply with the principle of "right of priority"[48].

Probably, what the Brazilian Proposal intends to highlight is that States Parties of the MERCOSUL are already bound by their international commitments. No further detail seems to be necessary in a future regional arrangement on patent protection for the MERCOSUL.

1.2. Non-obviousness

Another requirement for the patentability of an invention is the one which says that the invention must be a result of an "inventive step"[49]. The requirement of non-obviousness is also of general application throughout the world.

Article 11 (1), PLT, states that an invention will be patentable if it is a result of an inventive step, and further defines inventive step as follows:

> [a]n invention shall be considered to involve an inventive step (be non-obvious) if, having regard to the prior art as defined in paragraph (2), it would not have been obvious to a person skilled in the art at the

[47] *WTO Focus*, January-February 1995, N. 1, p. 5.
[48] Paris Convention, Art. 4, and TRIPS Agreement, Art. 2.
[49] Alternative A, Art. 10 (1) of the PLT; Art. 27 (1) of the TRIPS Agreement; Art. 52 (1) of the EPC; Art. 8 of the Law 9279/96; Section 5, Art. 1.1 of the Brazilian Proposal; and Art. 3 of the WIPO Proposal.

> filing date or, where priority is claimed, the priority date of the application claiming the invention.[50]

Firstly, it is necessary to note that the concept of "non-obviousness" is integrated with the requirement of novelty. The state of the art, as conceived here, is the same as that which will be used in the assessment of novelty. Once the invention has been legally interpreted as new, *i.e.* the invention is deemed not to form part of the prior art; such an invention shall also be non-obvious for a person skilled in the art. [51]

In short, what the law requires is that an invention shall have a substantial difference from what is already known (the obviousness of the invention). Further, the inventiveness of the invention will be assessed within the context of the knowledge of a person who is skilled in that specific art. This assessment shall be made taking into account the priority date which is claimed.

The discussion on non-obviousness is of immense complexity. The examiner, or the judge, will have to take into account, firstly, what is the prior art; then, whether the claimed patent has the technical features which represent a progress in the existing art. These new advantages or new uses of an invention will take into consideration the skilled knowledge of someone who has technical qualifications to judge that art and

---

[50]PLT, Art. 11 (3). Accordingly, other legislation interprets the subject in a similar manner. See, *e.g.*, Article 56 of the EPC, and Article 13 of the Law 9279/96. The latter includes the subject into the Brazilian industrial property law framework. Within the context of the parliamentary negotiations of the Law 9279/96 no controversy occurred in relation to the "non-obviousness" requirement.

[51]Generally speaking, the term "prior art" shall be understood as something that is already known. In order to involve an inventive step, therefore, an invention must establish a substantial development from what is known.

the improvements in question. That is why the disclosure of an invention is of great importance for assessing the inventiveness of a claimed invention.

As a means of encouraging research which might arise from the knowledge included in the invention, the application for a patent must disclose the invention. Such a disclosure shall be made utilising a clear, concise and precise form, "...as far as it is permitted to comprehend the technical problem and its solution, where the effects and advantages of the invention are disclosed, in relation with the state of the art"[52].

As better described by Cornish[53], the main point is that, for practical purposes, the skilled knowledge of the technician, "... armed with all the specific information and general knowledge deemed relevant, ..." as described in the application, should be applicable in so far as he "... could or should do what the patent proposes ...". Cornish suggests that the matter should be explored under two aspects: "proximity to the prior art" and the "technical advantages and commercial success" of the invention.

In relation to the proximity to the prior art, Cornish says that:

> ..., the fact that an idea escapes being anticipated only by the shortest remove will often jeopardise the chances of its being found inventive. Indeed, if the claimed invention is a "mere collocation" - where two known devices are to be placed side-by-side without any working inter-relationship - it will be more likely to be treated as a claim to discrete things separately anticipated.[54]

---

[52]Ato Normativo N. 19, of 11 May of 1976, Item 1.2 (e), as published in **INPI**, note 10, *supra*. The EPO considers the issue in a similar way. Decision T1/80 (BAYER/Carbonless copying paper), [1981] *Official Journal EPO* 206, has understood that the assessment of the inventive step "... has to be preceded by determination of the technical problem based on objective criteria" (the "problem-and-solution approach"). For further analysis of the "problem-and-solution approach", see **Gerald Paterson**, note 30, *supra*, para. 10-04, p. 423 and Rule 27 (1) (d), Implementing Regulations EPC. See, also, Chapter 4, Section 3, Sub-section 3.1, *supra*.

[53]**W.R. Cornish,** Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights, London: Sweet & Maxwell Ltd. (1989), 2nd ed., p. 134, para. 5-035.

[54]*Ibid.*, p. 134, para. 5-036.

With reference to the assessment of the technical advantage of an invention, this must be done taking into account the skilled knowledge of the technician. Usually, such an assessment will not happen at the application stage[55]. When discussing the commercial success of an invention as a means of assessing inventiveness, it is assumed that such a condition should take into account that "[c]ommercial success can help to demonstrate inventive character only if the invention is the cause of the commercial success", although in some cases this condition may be used as a "... persuasive indicator of inventiveness"[56].

As has been said, disclosure of the invention is an essential condition for the assessment of inventiveness. In this sense, the CPI did not require inventiveness as a requirement for the validity of a patent application. The INPI, on the other hand, considered that the result of an inventive activity, for someone skilled in the art, may not be an obvious result of the existing prior art, for the purposes of a patent application[57]. Though the national legislature did not include in the text of the CPI the requirement of inventiveness as a primary condition for the validity of a patent application, the INPI procedural and substantive concepts have included the inventiveness as a condition for the purposes of a patent application. Law 9729/96, which revokes the CPI, however, considers the inventiveness as a condition *sine qua non* for the patentability of the invention[58].

The negotiations of the PLT have not dealt in detail with the subject, apart from the US which has proposed that the first-to-invent approach should be allowed to exist in a Contracting Party for the assessment of the inventiveness of the

---

[55] *Ibid.*, p. 136, para. 5-037.
[56] *Ibid.*
[57] AN 17/76, Item 1.1 (e).

invention[59]. What is clearly a matter of discussion in this case is that the US wants to include in the text of the PLT a rule considering the first-to-invent system within the context of a Contracting Party which evaluates inventiveness as such, and that "... it [the Contracting Party] may make the evaluation as of the time the invention was made rather than at the filing date, or the priority date if one is claimed"[60]. Further, the representative of the US said that such a proposal shall only be considered in so far as the first-to-invent system is accepted in the text of the PLT.

In the context of the MERCOSUL, only Brazilian industrial property laws explicitly considers inventiveness as a basic condition for patentability. Argentinean law also requires inventiveness for the protectability of an invention, but the definition of inventive activity is included in the concept of absolute novelty and not as one of the conditions for patent protection. The laws of Paraguay and Uruguay do not refer at all to such a condition.[61]

While the WIPO Proposal suggests inventiveness as a condition for the patentability of an invention[62], defining inventiveness as being, for someone skilled in the art, not the result of an obvious prior art[63], the Brazilian Proposal merely says that

---

[58]See, *e.g.*, Law 9279/96, Arts. 8, 13 and 14.
[59]PLT/DC/6, as in PLT I Conf. Rec., pp. 122-123.
[60]*Ibid.*, at p. 123.
[61]See **MRE**, note 45, *supra*, p. 8; **WIPO**, Analisis Selectivo de la Legislacion de Propiedad Industrial de los Paises del MERCOSUR, Preparado por la Oficina Internacional de la OMPI (22/3/93), p. 2, paras. 5-7; and WIPO Doc. N. OMPI/MERCOSUR/MVD/94/2 (March 1994) Reunion de Expertos Gubernamentales Sobre Propiedad Intelectual en los Paises Miembros del MERCOSUR, Organizado por la OMPI en Coordinación con el Grupo Mercado Común del MERCOSUR y la Asistencia del Programa de las Naciones Unidas para el Desarrollo (14-15 Março 1994), p.12, paras. 34-36.
[62]WIPO Proposal, Art. 3.
[63]*Ibid.*, Art. 6.

States Parties shall grant protection to inventions which meet the requirement of inventiveness[64].

1.3. Usefulness

The condition that an invention has to be industrially applicable in order to be patentable is of common application in the laws of various countries. In the first place, both jurisprudence and doctrine have had some difficulty in defining the scope and the application of the usefulness of an invention. Some authors even tried to do so in the past, and wrongly mixed up the concept with other requirements for the validity of a patent application, *i.e.* novelty and non-obviousness. Others have tried to use the examples of jurisprudence to define the industrial applicability of an invention.[65]

The PLT, which suggests as a condition for patentability that an invention shall be either useful or industrially applicable, could not arrive at any definition of the terms in question[66]. It appears that the term "useful" was included to comply with the understanding of industrial applicability in the US.

In the EPC "[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture"[67]. The CPI says that "[a]n invention is considered susceptible of industrial application when it may be manufactured or industrially utilised"[68]. In Brazil, an invention is also

---

[64]Brazilian Proposal, Item 1.1.
[65]See, generally, discussion in **João da Gama Cerqueira**, note 19, *supra*, at pp. 99-103, para. 51.
[66]PLT I Conf. Rec., para. 928, p. 351.
[67]EPC, Art. 57.
[68]CPI, Art. 6 (3).

considered susceptible of industrial application if it may be produced for consumption and/or is applicable in at least one productive system.[69]

Gama Cerqueira has developed the doctrinal concept of industrial applicability as meaning:

> ... something which may be the object of industrial exploitation or which may be applicable in the industry. In this sense, the expression is applicable to the various types of patentable inventions, *i.e.* the invention of new "products" and the invention of new "means", including the processes, and the new "applications" and "combinations" of means already known to obtain an industrial result.[70]

In fact, the expression of industrial applicability which different laws utilise is closely related to the scope of the justifications of intellectual property protection, particularly the benefits that the invention is supposed to bring to society, which is considered by assessing its practical utility and technical means.

The requirement of usefulness, as a condition *sine qua non* for the granting of a patent, is also of general application in the national laws of the countries of the MERCOSUL. Working towards the harmonisation of national industrial property laws through a common regional agreement, the WIPO Proposal suggests that an invention has to be susceptible of industrial application as a condition for

---

[69] AN 17/76, Item 1.1.4 states that "[i]t is considered susceptible of industrial application the subject-matter of an invention which may be produced for consumption and/or applicable in at least one productive system". Aiming to be more precise, the negotiations on the PLC 115/93 determined in Article 15 that "[t]he invention and the utility model are considered susceptible of industrial application when they may be utilised or produced in any type of industry, including agriculture and manufactured or natural products". It is not clear why, but the final result of the Parliamentary negotiations of the PLC 115/93, *i.e.* Law 9279/96, excluded the last part "... including agriculture and manufactured or natural products" from the definition of "industrial applicability" (Law 9279/96, Art. 15). It seems that the Brazilian legislature decided to leave the matter to the implementing regulations issued by the INPI, which would be more easily updated *vis-a-vis* the international developments in the field of patent protection.

[70] **João da Gama Cerqueira**, note 19, p. 104, para. 52.

patentability[71]. Industrial application must be understood as occurring when the subject-matter of the patent may be utilised in any type of industry or productive activity[72]. For the purposes of the application of this definition, the WIPO Proposal further suggests that the term "industry" shall be considered in its broadest sense, including craft industries, agriculture, mining, fishing and other services[73]. Such a detailed definition is not included in the Brazilian Proposal, which merely suggests that States Parties shall grant patents to inventions which are industrially applicable[74].

As one might note from the discussion above, modern national/and or international laws have tried to define the expressions included in the definition of industrial applicability, or usefulness, but it appears that this will be a matter for examiners when a patent application is assessed, and for national judges in the case of a dispute.

1.4. Disclosure

A patent application must have a clear and complete description of the invention, in order to permit someone skilled in that art to arrive at the same, or a similar, result as the inventor. This requirement, normally included on the justification that a patent shall be fully disclosed to permit technological development and consequent benefit to society, is necessary to reveal the invention in a way that it could be regarded as useful information for industry, in general, and anyone who might have an interest in the patented invention.[75]

---

[71] WIPO Proposal, Art. 3.
[72] *Ibid.*, Art. 4, First sentence.
[73] *Ibid.*, Art. 4, Last sentence.
[74] Brazilian Proposal, Item 1.1.
[75] **W.R. Cornish**, note 53, p. 150, para. 5-058.

The description of an invention is generally divided in two parts; the introduction and the description itself. In the first part, the applicant must describe the state of the art and all the information related to the invention which is already within the public domain and might be deemed useful for the understanding of the invention. In the second part - the description itself - the applicant must disclose all the technical information related to the invention, its functions and aims, as well as a the description of the ways the invention may work.[76]

During the GATT negotiations no controversy existed in this field. Negotiating countries - both developed and developing - generally agreed upon the requirement that inventors must fully disclose the invention for the purposes of filing a patent application[77]. Thus, Members of the WTO Agreement must "... require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete..." in so far as the invention could be carried out by someone skilled in the art[78].

In Brazil, it is required that patent applicants must describe the invention in a clear, concise and precise way, permitting the comprehension of the technical problem and of the respective solution. The applicant shall also highlight the effects and advantages of the invention in relation to the state of the art.[79] Furthermore, the applicant must describe the methods which shall be used to carry the invention out so

---

[76]**João da Gama Cerqueira**, note 19, *supra*, pp. 158-162. *Cf.* AN 19/76, Item 1.5 (d), and Law 9279/96, Arts. 24 and 25.

[77]See, *e.g.*, GATT Doc. N. MTN.GNG/NG11/W/17 (23 November 1987) Suggestion by Japan for Achieving the Negotiating Objective, p. 6, and; GATT Doc. N. MTN.GNG/NG11/W/57 (11 December 1989) Communication from Brazil, p. 4, para. 20, for similar positions of a developed and a developing country, respectively.

[78]TRIPS Agreement, Art. 29. Under the mandatory obligation of Article 29, there is also a non-obligatory legal statement that Members may "... require the [patent] applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application".

that someone skilled in the art could repeat the invention[80]. Further, while Article 24 of the Law 9279/96 requires disclosure as one condition for filing a patent application, Article 25 states that a patent application shall contain a descriptive report of the invention, highlighting the particularities of the application and defining, in a clear and precise way, the subject-matter which shall be protected.

In the context of the MERCOSUL, it seems that no further discussion will be held on this matter. The national laws of the four countries require the disclosure of the invention, in a clear and precise way, as a basic condition for the patentability of the invention. Also, both the WIPO Proposal and the Brazilian Proposal have considered the disclosure of an invention as a condition for the protectability of an invention[81].

2. *EXCLUSIONS AND EXCEPTIONS*

Not only the requirements discussed above will be used for the assessment of the validity of a patent application. A further condition for the patentability of an invention is that it may not be either excluded from patentability or unlawful. The EPC makes a distinction between what is excluded from patentability; *i.e.* what shall not be deemed as an invention; and what may be considered an invention but shall not be protected because it is against the law[82]. Such a distinction is not clearly established in the different legal instruments which have been analysed in this Chapter, apart from the EPC and Law 9279/96. The CPI, for instance, does not provide for such a distinction and merely refers to "non-patentable inventions", including what is

---

[79]AN 19/76. Item 1.2 (e).
[80]*Ibid.*. Item 1.2 (h).

excluded and what are the exceptions in a single list. This Section does not intend to discuss such a distinction. In fact, both categories mean that the subject-matter is not capable of patent protection.

The text of the TRIPS Agreement does not impose a system of exclusions. It simply says that Members of the WTO Agreement may exclude from patentability (but are not obliged to do so) inventions against public order, morality, human, animal or plant life or health, and inventions which shall cause damage to the environment[83]. Further, the TRIPS Agreement gives Members the possibility of excluding from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals[84], as well as "plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes"[85].

The CPI lists what shall not be patentable, by affirming that what is against law, morality, health, public order, religions and feelings which are a matter for respect shall not be protected[86]. Further, Article 9, CPI, excludes from patentability the following: (a) a product which is a result of a chemical process[87]; (b) foodstuffs, chemical-pharmaceutical products and drugs of any type, including its process[88]; (c)

---

[81] WIPO Proposal, Art. 15 (c), and Brazilian Proposal, Item 6.2.
[82] See, also, Chapter 4, Section 3, Sub-section 3.2, *supra*, for the analysis in the EPC.
[83] TRIPS Agreement, Art. 27 (2). Further, the last sentence of this provision says that Members are allowed to excluded these subject-matters from patentability in so far as "...such exclusion is not made merely because the exploitation is prohibited by their law".
[84] *Ibid.*, Art. 27 (3) (a).
[85] *Ibid.*, Art. 27 (3) (b). This provision will be reviewed four years after the entry into force of the WTO Agreement (TRIPS Agreement , Art. 27 (3) (b), last sentence). Also, this provision states that Members shall protect plant variety rights. Further discussion on biotechnology and plant variety protection is in Sections 2 and 3, Part 2, *infra*.
[86] CPI, Art. 9 (a).
[87] *Ibid.*, Art. 9 (b). Note that chemical processes are patentable, what is excluded from patentability are chemical products.
[88] *Ibid.*, Art. 9 (c).

metal alloys[89]; (d) the combination of known processes and the mere modification of size, dimensions and forms of materials[90]; (e) discoveries, including varieties or species of micro-organisms[91]; (f) diagnostic, therapeutic and surgical methods, excluding tools and machines[92]; (g), systems, programs, plans, accounting methods for commercial purposes, for calculations, financing, credit, drawing by lots, speculation or marketing[93]; (h) theoretical conceptions and products and processes involving the atomic nucleus[94,95]

Article 10 of the Law 9279/96 states that the following shall not be regarded as inventions:

> I-discoveries, scientific theories and mathematic methods;
> II-purely abstract conceptions;
> III-schemes, plans, principles and methods of trade, accounting, finance, education, publicity, fiscalisation and lottery;
> IV-literary, architectural, artistic and scientific works or any aesthetic creation;
> V-computer programs as such;
> VI-presentations of information;
> VII-rules for playing games;
> VIII-surgical techniques and therapeutic or diagnostic methods, for application within the human or animal body; and,
> IX-the whole or part of a natural living organism and biological materials as found in nature or isolated from the latter, including the genoma or germoplasm of any natural living organism and natural biological processes.

---

[89] *Ibid.*, Art. 9 (d).
[90] *Ibid.*, Art. 9 (e). Under the CPI, if such a combination or modification was understood as involving a new technical effect, which was not prohibited by the law, they would be protectable.
[91] *Ibid.*, Art. 9 (f). See, further, discussion in Section 2, Part 2, *infra*.
[92] *Ibid.*, Art. 9 (g).
[93] *Ibid.*, Art. 9 (h).
[94] *Ibid.*, Arts. 9 (i) and (j), respectively.
[95] Note, however, that as a result of the publication of Law 9279/96, chemical products and processes, foodstuff, chemical-pharmaceutical products, including its process, and transgenic micro-organisms, are capable of patent protection. The protection of pharmaceutical products and processes, biotechnology and plant varieties will be further discussed below, in Part 2.

The exclusions provided by Law 9279/96 are generally applied by the laws of different countries. The exclusions of discoveries, scientific theories, mathematical methods and purely abstract conceptions from the concept of invention is necessary in order to draw a line between what the law will consider an invention and what it will not. The same applies to schemes, plans, principles and methods in general, presentation of information and rules for playing games. It is necessary to remark that they are excluded from patent protection "...only to the extent that the patent relates to the conception 'as such'"[96]. It is not clear however if the same could apply also to computer program in the context of the application of Brazilian national legislation[97].

With regard to the non-inclusion of literary, architectural, artistic and scientific works or aesthetic creations and computer programs within the concept of invention, another justification for exclusion is found. They are all protected under alternative system of laws; generally their protectability will be assessed under the principles of copyright protection.[98]

In relation to the exclusion of methods and techniques for treating the human or animal body, this is generally based on lack of industrial applicability and, also, because such methods and techniques, under a public policy approach, should be disseminated without restrictions.[99]

The last exclusion listed in Law 9279/96 is related to the limitation upon biotechnology processes and products. As generally provided, neither natural living

---

[96]**W.R. Cornish**, note 53, *supra*, p. 139, para. 5-041. Cornish, in pp. 139-141, paras. 5-041 to 5-044, discusses further the application of the exclusions of discoveries and presentation of information.

[97]*Cf.* Chapter 4, Section 3, Sub-section 3.2, *supra*, which describes that only computer programs *per se* are excluded from patentability within the EPO, but computer programs which are essential part of an invention may be protected as within the whole context of the invention.

[98]See, generally, Art. 52 (2), EPC, and Section 1, Part II, of the TRIPS Agreement. See, also, **W.R. Cornish**, note 53, *supra*, pp. 141-145, paras. 5-045 to 5-050.

organisms, nor their varieties, are patentable. Although the TRIPS Agreement accepts that plant varieties, for instance, could be patentable, it also states that Members of the WTO Agreement should have the choice of establishing a *sui generis* system of protection or any combination of such protection with patent protection.

The Law 9279/96, in Section III, provides that some inventions and utility models are not patentable. Thus, it simply lists what, although considered an invention, will not benefit from patent protection.

> Art. 18 - The following are not patentable:
> I-what is against morality, good habits and public security, order and health;
> II-substances, materials, mixtures, elements or products of any type, as well as the modification of their physic-chemical properties and their respective processes for obtention or modification, when resulting from the transformation of the atomic nucleus; and
> III-the whole or part of living organisms, excluding transgenic micro-organisms which fulfil the three requirements of patentability - novelty, inventive activity and industrial applicability - listed in Article 8 and which are not discoveries.

The first exclusions from patent protection are generally those in respect of morality, public order, health and security[100]. The prohibition on protecting inventions which are against morality or public order is difficult to assess. There is no example of an invention which is itself against the morality or the public order, although the EPO has considered this issue in a controversial application[101]. Actually, what may be considered against morality or public order is the future use that will be given to an invention. Of course, the law must not protect an invention which is against morality

---

[99]**W.R. Cornish**, note 53, *supra*, p. 145, para. 5-052.
[100]The CPI also excluded from patentability what is against the law. It is however clear enough that what is against the law is not protectable at all and that there is no need to include it in the text of industrial property laws. Law 9279/96 therefore has not provided so.
[101]Decision T19/90 (HARVARD/Onco Mouse) [1990] EPOR 50.

or public order but, as described by Gama Cerqueira, "[t]he examples of this type of inventions are generally within the realm of theory and the imagination"[102]. What the law rules is merely that the invention which could only be used against morality or public order will not be patentable. The legislator also included as an exception inventions which are contrary to good habits. According to what has been discussed in this paragraph, one will hardly find such an invention. Actually, what could be against good habits is the further use of such an invention.

The law also says that inventions which are against public security shall be excluded from patentability. In fact, what could be understood from the wording of the law is that these are the inventions which are of interest for national defence or general military use, not those which are a matter of public health. This is another issue to be discussed. Gama Cerqueira does not agree that there is a need to include such an exception. He recalls that one will rarely find an invention which, by itself, is contrary to public security. Further, Gama Cerqueira says that if it is not contrary to the public security, but militarily necessary, the State has appropriate legal measures to expropriate the patent when it deems necessary, such as, *inter alia*, the use of compulsory licences.

An invention which could be used against public health is also precluded from patentability. In this case one will find the example provided by the TRIPS Agreement, which excludes from patentability inventions which could jeopardise human, animal or plant life or health or which could cause prejudice to the environment. Generally speaking this exclusion is related to foodstuffs and medical

---

[102] **João da Gama Cerqueira**, note 19, *supra*, p. 110. In fact, Gama Cerqueira goes further and says that what the law excludes is the invention which is itself against the morality, not the probable use of it.

products which could cause damage to human, plant or animal health. This is a limitation which will be analysed within a context of a product, a tool or a machine which will undoubtedly cause damage to the health of the public. Further, with regard to the protection of the environment a more modern approach has been taken towards the issues formally raised by the United Nations Conference on Environment and Development (UNCED), held at Rio de Janeiro, Brazil, in June 1992[103].

Lastly, Law 9279/96 excludes the protection of the whole or part of living organisms, excluding transgenic micro-organisms which are not discoveries and fulfil the requirements of novelty, inventiveness and industrial applicability. This has been a matter of controversy over ethical considerations in the Brazilian parliament, and will be further discussed in this Chapter in Part 2, Section 2, Sub-section 2.2, *infra*.

In general, national laws of the States Parties of the MERCOSUL appear to be to the same effect. The WIPO Proposal has suggested that the following should not be considered inventions: discoveries, scientific theories, mathematical methods[104], aesthetic creations[105], purely intellectual activities, plans, principles or methods for economics and business[106], the presentation of information[107], and therapeutic, surgical and diagnostics methods for the treatment of humans or animals[108]. Further, the WIPO Proposal has suggested that States Parties of the

[103]Further discussion in relation with the outcome of the UNCED is discussed in more detail in Chapter 7, *supra*.
[104]WIPO Proposal, Art. 1 (2) (a).
[105]*Ibid.*, Art. 1 (2) (b).
[106]*Ibid.*, Art. 1 (2) (c).
[107]*Ibid.*, Art. 1 (2) (d).
[108]*Ibid.*, Art. 1 (2) (e).

MERCOSUL should be allowed to exclude from patentability inventions which are against morality or public order[109].

The Brazilian Proposal, on the other hand, suggests only that States Parties of the MERCOSUL may consider as not patentable inventions which are against morality, good habits, security and order or public health.[110]

While the WIPO Proposal suggests the general standards of exclusions and exceptions, avoiding discussing the subject of pharmaceuticals, plant varieties and biotechnology, the Brazilian Proposal includes, only, what is already a matter of agreement in the laws of the countries of the MERCOSUL. It seems that neither provision is necessary within the context of a regional agreement. If an agreement needs to be reached, it should address the most controversial and non-harmonised issues, such as pharmaceuticals, biotechnology and plant varieties. Though the latter subjects are controversial and of common agreement among developing countries, a policy strategy should be put forward in so far as sooner or later all States Parties of the MERCOSUL will have to comply with their international commitments, in particular those of the TRIPS Agreement.

3. RIGHTS CONFERRED BY A PATENT

The privilege granted to an invention entitles the successful applicant to the proprietorship and the exclusive right over the patented product or process for a limited period of time. The patent holder has therefore the right to manufacture and exploit his invention commercially, to assign his rights, to conclude licensing contracts

---

[109] *Ibid.*, Art. 2 (1).
[110] Brazilian Proposal, Item 1.2.

and to transfer the privilege by succession. The patentee has also the right to prevent third parties, without his consent, from acts of making, using, offering for sale, selling, importing, exporting, or stocking a patented product or the process or product obtained by a patented process. Different laws also establish the obligations of the patent holder. For instance, the proprietor of a patent must disclose and work the invention, as well as pay the fees, provide the patent office with the required documents, etc. Several of these obligations have been, or will be, generally discussed throughout this thesis.

Different laws also provide for some restrictions and limitations of these rights, such as the compulsory licensing mechanism. This Section will discuss generally the basic rights of a patentee and issues about compulsory licences

3.1. Basic rights

According to Gama Cerqueira, the temporary privilege granted to the inventor includes a positive and a negative aspect. The positive aspect includes the right to use, exploit and transfer, assign or licence the patented product or process. The negative aspect includes the right to prevent someone from using, selling, offering for sale, importing, exporting, etc.[111] To sum up, the bundle of rights conferred by the patent privilege to the patent holder is: (a) the right to exploit the invention, (b) the right to exploit the patent itself, and (c) the right to impede third parties from exploiting the patent without the patentee's authorisation.

Firstly, the right to exploit the invention will be considered as those related to the manufacturing, selling or offering for sale of the invention or the industrial use of

it. Secondly, the right to exploit the patent is included in the right to assign, transfer or license the patent. Finally, the right to impede someone from exploiting the patent in any way is the right to claim, judicially or administratively, infringements against the patent.[112]

The right to use and exploit the invention commercially is at the same time an obligation, in so far as the patented invention has to be used in order to fulfil the requirements of the law. It is not necessary that the proprietor of a patent uses, manufactures or puts into the market the patented invention. He may authorise someone else to do so or he may sell his rights over the invention.

The patent holder may also exploit the patent itself. He may, for instance, assign the proprietorship over that invention by act *inter vivos* or *causa mortis*. The assignment may be onerous or gratuitous. Actually, the assignment, as such, is a legal transfer of the proprietorship of the inventor. In this case the patentee must specify what has been sold or given. The patent holder, for example, may assign the patent fully or partially. He fully assigns the patent when all the rights over the invention are transferred or sold to someone else without any restriction, for the full term of the operation of such patent. He partially assigns the patent when he transfers or sells only parts of the rights included in his privilege.

It is important, however, that the assignment is not mixed up with a licensing contract. While in an assignment contract the patent holder transfers the ownership of the patent to someone else, in a licensing contract he merely authorises someone to use, manufacture, sell, offer for sale, import or export the patented product or

---

[111] **João da Gama Cerqueira**, note 19, *supra*, p. 197.
[112] *Ibid.*, p. 198.

process. In the case of a licensing contract, the ownership of the patent remains with the patentee. There are several consequences of licensing contracts which are discussed further in Chapters 3, *supra*, and 6, *infra*.

Finally, it is noteworthy that the owner of a patent has the right to prevent the unauthorised use of the patented product or process. He may claim his rights and infringements if someone, without his consent, exploits his patent.

The rights conferred by the patent are generally provided in different legal frameworks. Some light controversy, however, has arisen from the negotiations of the PLT. Developing countries have affirmed that the rights conferred by a patent should consist only of the rights of making, selling and using the patent product "... while whether or not the patent confers a right of importation should be left to the national laws"[113] and that "[t]hey should not extend the protection to products directly obtained from the process because it could allow extension of protection to unpatentable subject-matter, or extend the term of a product patent that should have lapsed"[114]. In general, it is possible to say that international, regional and national laws provide similar rights for the patentee and there is not a heated debate on this subject.

3.2. The issues on compulsory licences

The mechanism of a compulsory licence may be defined as a legal tool which authorises national authorities to grant a licence, without the patentee's consent, to someone who is capable of producing the patented product or for government use[115].

---

[113]PLT I Conf. Rec., p. 509, para. 114.10.
[114]*Ibid.*, para. 114.11.
[115]A compulsory licence is also called a non-voluntary licence. The TRIPS Agreement, for instance, avoided the use of such term and called it "Other Use [of a patent] Without the Authorization of the Right Holder" (Title, Article 31). It is also worth noting that the CPC defined the term for the

Norms on compulsory licences exist in the patent laws of the majority of the countries of the Paris Union - the major exception being the US[116] -, but the grounds for the issue of a non-voluntary licence vary substantially between the laws of different countries.[117] The variety of issues included in the compulsory licence discussion has been of great relevance during multilateral and national negotiations and that has caused major controversial discussions among developed and developing nations.

The Paris Convention refers generally to the right of Members of the Paris Union to grant compulsory licences on grounds of failure to work or insufficient working of a patent[118]. The Paris Convention says that Members are allowed to provide for the mechanism of a compulsory licence and further rules that Members may grant a compulsory licence on the ground of failure to work or insufficient working only after "...a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; ..."[119]. Such a licence "... shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-licence, ..."[120].

The Paris Convention also states that Members shall accept the importation of products which have been manufactured in any of the countries of the Paris Union as within the understanding that a patent has been used. The patent shall not therefore be

---

application of a compulsory licence within the European Community "... as including official licences and any right to use patented inventions in the public interest" (Agreement Relating to Community Patents, Chapter 4, note 16, *supra*, Art. 45 (4)).

[116]According with **Tom Arnold & Ed Goldstein**, Compulsory Licensing: The "Uncentive" for Invention, [1975] 7 *Patent Law Review* 113, however, the US generally provides compulsory licensing mechanisms through legislation regulating federal government activity and case law.

[117]See, *e.g.*, list provided by GATT Doc. N. MTN.GNG/NG11/W/24/Rev.1 (15 September 1988), Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, pp. 11-12.

[118]Paris Convention, Art. 5 (A) (2).

[119]*Ibid.*, Art. 5 (A) (4).

[120]*Ibid.*

forfeit for that reason[121]. The concerns with local production as against importation as a means of using patents have probably been the cutting edge of the compulsory licence debate. While developing countries understand that the use of a patent has to be on the basis of local production[122], industrialised nations propose that importation shall be sufficient for the use of a patented product[123]. At the end of the day, the negotiations in the Uruguay Round favoured the viewpoint of developed nations. The TRIPS Agreement affirms in Article 27 (1) that "...patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and 'whether products are imported or locally produced'"[124] and, consequently, Members of the WTO Agreement shall comply with importation as a means of working of a patent.

The PLT also suggests the inclusion of the compulsory licence in its text. The PLT proposes, as one of the alternatives, that "...any Contracting State is free to provide, ..., on grounds of public interest, national security, nutrition, health, or the development of other vital sectors of the national economy, ..."[125] for the granting of a compulsory licence[126, 127].

---

[121] *Ibid.*, Art. 5 (A) (1).

[122] See, *e.g.*, Indian, Peruvian and Brazilian proposals in GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2 (2 February 1990) Synoptic Tables Setting Out Existing International Standards and Proposed Standards and Principles, Prepared by the Secretariat, Revision, at pp. 97 and 101, respectively.

[123] See, *e.g.*, proposals of the United States and Switzerland in GATT Doc. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, at pp. 96 and 98, respectively.

[124] Emphasis added. See, also, **Carlos Correa**, The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection, [1994] 8 *EIPR* 327-335, p. 331.

[125] PLT, Alternative B, Art. 26.

[126] The text of the PLT refers to compulsory licences as "non-voluntary licences".

[127] There are two alternatives for Article 26 of the PLT. Alternative A proposes that there should be no provision on the matter and Alternative B proposes a general framework, as mentioned above. Developing countries favoured Alternative B as "...vital in insuring the balance between the exclusive rights conferred by patent and the obligations patent holders have to the public" (PLT I Conf. Rec., pp. 509-510, para. 114.14). On the other hand, some developed countries, as well as China and the Soviet Union, supported the non-inclusion of any regulations on compulsory licence

This subject was discussed and analysed in more detail during the negotiations towards the TRIPS Agreement. The most important trading nations emphasised, from the very beginning of the negotiations, that the matter was of concern, and that a final agreement on TRIPS should address the issues properly[128]. The agreed text of the TRIPS Agreement accepts that the law of the Members of the WTO Agreement could provide for the use of a compulsory licence, in so far as certain conditions are met. The grounds for the granting of a compulsory licence are, as non-exhaustively listed in the TRIPS Agreement, government use[129], lack of sufficiency of working the patent[130], a remedy against anti-competitive practices[131], national emergency[132] and dependent patents[133]. [134]

The granting of compulsory licences is nevertheless limited to a certain extent and can only happen under certain conditions. Thus, Members shall, if allowing the mechanism of a compulsory licence, respect the conditions listed below: (a) authorisation to grant a compulsory licence has to be considered on its individual

---

(PLT I Conf. Rec., pp. 512-513, paras. 116.15, 116.16 and 116.17; pp. 514-515, para. 118.11; and p. 516, para. 120.8, respectively).

[128]See, *e.g.*, GATT Doc. N. MTN.GNG/NG11/W/2 (3 April 1987), Statement by United States at Meeting of 25 March 1987, p. 2 and GATT Doc. MTN.GNG/NG11/W/7 (29 May 1987), Submissions from Participants on Trade Problems in Connection with Intellectual Property Rights, p. 4, for the submission by the European Communities; pp. 9-10, for the submission by Japan, and; pp. 26-27, for the submission by the United States.

[129]TRIPS Agreement, Art. 31, *caput*.

[130]Or "public non-commercial use", as referred to in Article 31 (b) of the TRIPS Agreement.

[131]TRIPS Agreement, Art. 31 (k). Members will not be required to apply the following conditions: (a) prior failed negotiations with the patent holder has to happen (*Ibid.*, Art. 31 (b)); and (b) the compulsory use may be authorised predominantly for the supply of the domestic market authorising the non-voluntary use (*Ibid.*, Art. 31 (f)).

[132]*Ibid.*, Art. 31 (b).

[133]*Ibid.*, Art. 31 (l).

[134]Note that the examples of grounds for the use of a compulsory licence as listed in the TRIPS Agreement are a minimum requirement. Members of the WTO Agreement are, at least in theory, allowed to establish other grounds for compulsory licences. See, *e.g.* **Carlos Correa**, note 124, *supra*, p. 331.

merits[135]; (b) failed efforts to obtain authorisation from the right holder have to precede the granting of the licence[136]; (c) the scope and the duration of a non-voluntary licence will be limited to the purpose for which it was authorised[137]; (d) the licence shall be non-exclusive[138] and non-assignable[139]; (e) the use shall be granted only for the supply of the domestic market of the country which authorises the non-voluntary use[140]; (f) adequate remuneration shall be paid to the right holder[141]; (g) any decision relating to the granting of a compulsory licence shall be subject to judicial or administrative review[142]; and (h) where a non-voluntary licence is provided to permit the exploitation of a second patent[143], the invention protected by a second patent shall involve an important technical advance in relation to the invention of the first patent[144]. The owner of the first patent shall be entitled to a cross-licence in respect of the second patent[145] and the use of the first patent shall not be assignable, except with the assignment of the second patent[146].

Most of the issues included in Article 31 of the TRIPS Agreement have been generally proposed by the representatives of different countries, mostly by the delegations of the industrialised nations. The US, for instance, has proposed that a

---

[135]TRIPS Agreement, Art. 31 (a).
[136]*Ibid.*, Art. 31 (b). It is also necessary to note that this requirement may be waived by Members in the case of national emergency or public non-commercial use. The patent holder shall be communicated "as soon as reasonably practicable", in cases of national emergency, and "promptly", in cases of non-commercial use.
[137]*Ibid.*, Art. 31 (c). Note, in addition, that a compulsory licence shall be revoked if "... the circumstances which led to it cease to exist and are unlikely to recur" (*Ibid.*, Art. 31 (g)).
[138]*Ibid.*, Art. 31 (d).
[139]*Ibid.*, Art. 31 (e).
[140]*Ibid.*, Art. 31 (f). Members are not obliged to apply this provision when a compulsory licence is granted "... to remedy a practice determined after judicial or administrative process to be anti-competitive" (*Ibid.*, Art. 31 (k)).
[141]*Ibid.*, Art. 31 (h).
[142]*Ibid.*, Art. 31 (i).
[143]*Ibid.*, Art. 31 (l).
[144]*Ibid.*, Art. 31 (l) (i).
[145]*Ibid.*, Art. 31 (l) (ii).

compulsory licence should be available in the TRIPS Agreement solely to address a case of national emergency or to adjudicate violation of competition laws, as well as for the use of the government. The delegation of the US has proposed further that, for these cases, a compulsory licence should be non-exclusive, just compensation should be paid to the patentee and that all decisions on the granting of a compulsory licence, as well as the compensation to be paid to the patentee, should be subject to judicial review.[147]

Within the EU, the CPC rules upon the granting of a compulsory licence for lack or insufficiency of exploitation[148] and in respect of dependent patents[149]. The CPC also respects the national provisions on compulsory licences, but restricts its application to the territory of the Member State which granted a specific compulsory licence[150].

---

[146]*Ibid.*, Art. 31 (l) (iii).

[147]GATT Doc. N. MTN.GNG/NG11/W/14/Rev.1 (17 October 1988), Suggestion by the United States for Achieving the Negotiating Objective - Revision, p. 4. At this point, the issues on TRIPS were addressed in a general basis. Accordingly was the position of Japan. See, *e.g.* GATT Doc. N. MTN. GNG/NG11/W/17 (23 November 1987), Suggestion by Japan for Achieving the Negotiating Objective, p. 6, and GATT Doc. N. MTN.GNG/NG11/W/17/Add.3 (8 December 1989), Submission by Japan - Addendum. The European Communities initially addressed the subject saying that any national provision allowing for the granting of a compulsory licence should "..., be to review by a court of law"; in GATT Doc. N. MTN.GNG/NG11/W/26 (7 July 1988), Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights, p. 6.

[148]CPC, Art. 46. Such a provision rules on the understanding of the use of a compulsory licence. It says that importation, within the territory of the Community, shall be considered as use of a patent in so far as it was put into the market "... in sufficient quantity to satisfy needs in the territory of that other Contracting State". Further, the CPC says that such a provision will not apply for compulsory licences granted on grounds of public interest.

[149]*Ibid.*, Art. 47. In relation to the granting of a compulsory licence which is dependent on a first patent, Article 47 says that it "... shall be applicable to the relationship between Community patents and national patents and to the relationship between Community patents themselves". Actually, what appears to have been the aim of the negotiators, with regards to this provision, is that once the CPC will be into force, it will have two types of patents: Community patents and national patents. The negotiators probably just made clear that in the case of a dependent patent both are going to apply.

[150]*Ibid.*, Art. 45 (1).

In Brazil, the CPI permits the granting of a compulsory licence on grounds of lack of effective exploitation of the patent[151] and public interest[152].[153] The CPI provides also for some conditions: the patentee may oppose the granting of a compulsory licence[154], but in the case where he is not successful he may observe and examine the production, the selling and the proper use of the invention, demand the payment of the fixed royalties[155], and request the annulment of the compulsory licence when he can prove that the requirements of the law have not been met by the licensee[156]. On the other hand, the licensee has the duty to initiate the effective exploitation of the patent within twelve months from the date the compulsory licence is granted and he may not interrupt the use of the patent for a period of more than one

---

[151]CPI, Art. 33. Actually, what the CPI says is that the holder of a patent will be obliged to give a licence to someone who has asked for permission to exploit such a patent, if the patentee has not effectively initiated the use of the patent within three years from the granting of the patent, or if the patentee has interrupted the use of the patent for a period of more than one year. Note, that this licence, opposing to the provisions of the Paris Convention, is granted on an exclusive basis. The CPI further considers that the importation may be used as a proof of the use of a patent in the case of a international agreement in which the country is a participant (*Ibid.*, Art. 33 (2)). Furthermore, Article 52 of the CPI rules that it is considered an effective exploitation of an invention, in industrial scale, either by the production of it by the patentee or by the granting of licences to third parties to produce the invention. As a result of the ratification of the Stockholm revision of the Paris Convention (by Decree N. 635, of 21 August 1992) Brazil shall grant compulsory licence in a non-exclusive basis (Paris Convention, Art. 5 (4)).

[152]*Ibid.*, Art. 33 (1). The granting of a compulsory licence on grounds of public interest will be allowed, non-exclusively, if the effective exploitation of the patent does not fulfil the needs of the market.

[153]The CPI also provides in Article 39 and Articles 44 to 47, that a patent may be expropriated on grounds of national security interest. The concept here is not the same as that of a compulsory licence. The CPI separately deals with the issues on the granting of a licence on grounds of national security interest, for government use.

[154]CPI, Art. 34 (3). The patent holder is allowed only to oppose the granting of a compulsory licence administratively. **Gama Cerqueira**, note 19, *supra*, at p. 240, affirmed that only the national courts may revise the right of the inventor, secured by the patent. However, Gama Cerqueira was referring to the legislation at that time. Today, constitutional provisions refer to the right to have an administrative decision, taken by a public authority (see, *e.g.*, Art. 5 (LXIX) and Art. 109 (VIII), Brazilian Constitution).

[155]CPI, Art. 36.

[156]*Ibid.*, Art. 37. *Cf.* Arts. 35 and 36, CPI, for the conditions of the law which shall be met by the licensor.

year[157]. The licensee shall also pay the royalties decided by the national authority to the patentee and make proper and adequate use of the patented product[158].

Law 9279/96, aiming to go further into the matter, allows for the granting of a compulsory licence as follows: (a) on grounds of anti-competitive practices[159]; (b) non-exploitation of the subject-matter of the patent within the national territory, or the lack of the total use of a patented product[160]; (c) if the needs of the market have not been satisfied by the actual commercialisation[161]; (d) in cases of public interest or national emergency[162]; and (e) dependent patents[163].

Further, Law 9279/96 establishes some conditions. It says that a compulsory licence may be requested by anyone who has a legitimate interest as well as technical and economic capacity to exploit efficiently the subject-matter of the patent. Such a licence must be predominantly addressed to the national market[164]. The compulsory licence may be granted only after a period of three years from the date of the granting

---

[157]*Ibid.*, Art. 35.
[158]*Ibid.* Art. 36.
[159]Law 9279/96, Art. 68, *caput*. These grounds for the granting of a compulsory licence may be considered if the abusive use of the right conferred upon a patent or the abuse of economic power is proved by administrative or judicial decision (*Cf.* TRIPS Agreement, Art. 31 (k)). If the compulsory licence has been granted on grounds of abuse of economic power, the licensee who has proposed local production of the patented product, has, in addition, one year to carry on importation of the patent. Within this first year, the licensee must initiate the exploitation of the patent. Such importation, however, may be made only from a place where the patent was put into the market by the patentee himself or by someone with his consent (Law 9279/96, Arts. 68 (3) and (4), and 74).
[160]*Ibid.*, Art. 68 (1) (I). The importation of the patent will be allowed, however, if the patentee proves that local production is economically impossible. A controversial discussion which has arisen from this provision is that Law 9279/96 links the forfeiture of a patent with the compulsory licence concept. Article 80 of the Law 9279/96 says that the patent will forfeit if after two years from the granting of a compulsory licence, such a measure has not been sufficient to prevent the abuse or lack of use of the patent.
[161]*Ibid.*, Art. 68 (1) (II).
[162]*Ibid.*, Art. 71.
[163]*Ibid.*, Art. 70.
[164]*Ibid.*, Art. 68 (2). However, in the case of a compulsory licence required on grounds of anti-competitive practices, the person who has required it has to prove by documents the decision upon such an anti-competitive practice (*Ibid.*, Art. 73 (2)).

of the patent[165]. Also, a compulsory licence shall be non-exclusive and is not subject to a sub-licence[166]. The patentee may oppose the grant of a compulsory licence[167], but in the case of the granting of a compulsory licence on grounds of lack of or insufficient use, the patentee is bound to prove the exploitation of the invention[168]. The decision on the adequate payment for the patent holder, which is to be taken on a case-by-case basis, must consider the economic value of the licence[169]. The licensee is bound to exploit the subject-matter of the patent within one year from the date the licence was granted[170]. If he does not do so, the patent holder may request the annulment of the licence[171].

Within the MERCOSUL, the Brazilian Proposal suggests that national law is free to determine the grounds in which the granting of a compulsory licence will take place[172] but, in some cases, limitations apply. If the text proposed by the Brazilian government becomes a treaty to regulate patent protection within the MERCOSUL, States Parties will be obliged to meet the following conditions. A compulsory licence will be granted only if the person who requires the licence has made every effort, in reasonable terms, to obtain a voluntary licence from the patent holder, but failed to get a licence from the patentee[173]. This will not apply for compulsory licences granted on grounds of national emergency, other cases of extreme urgency, in case of public

---

[165]*Ibid.*, Art. 68 (5).
[166]*Ibid.*, Art. 72.
[167]*Ibid.*, Art. 73 (1) and (4).
[168]*Ibid.*, Art. 73 (3).
[169]*Ibid.*, Art. 73 (6).
[170]*Ibid.*, Art. 74, *caput*.
[171]*Ibid.*, Art. 74 (1).
[172]With the exception of compulsory licences granted on grounds of a dependent patents. In this case, Item 7.2.1. of the Brazilian Proposal suggests that a compulsory licence will be granted if a situation of dependency from one patent to the other exists and the second patent is a substantial technical and economic progress in relation with the first patent and when the holder of the first patent has not agreed with the holder of the dependent patent for the exploitation of the former.

non-commercial exploitation, or when an anti-competitive practice is deemed to have occurred[174]. In these cases the patent holder shall be notified at once[175].

Furthermore, a compulsory licence shall be non-exclusive[176], the scope and term of the licence shall be limited to the aim of the authorisation[177], the licence is not assignable[178] and a compulsory licence will apply solely to meet the needs of the national market of the country which has granted it[179]. A compulsory licence shall exist only during the period that the circumstances which have supported the compulsory licence remain the same[180].

The patent holder shall receive adequate remuneration for the non-voluntary use of his patent, and this remuneration shall take into account the economic value of the licence[181]. Decisions upon remuneration shall be subject to judicial control[182] as well as the judicial validity of any decision related to the granting of a compulsory licence[183].

The foregoing description of compulsory licences is not exhaustive. The issue is controversial. The relevance of this legal mechanism is nevertheless doubtful and its applicability is rare on a world-wide basis.[184] The issue raises controversy, because developed nations usually see the mechanism of compulsory licence as a possible tool

---

[173]Brazilian Proposal, Item 7.2 (a).
[174]*Ibid.*
[175]*Ibid.*
[176]*Ibid.*, Item 7.2 (c).
[177]*Ibid.*, Item 7.2 (b).
[178]*Ibid.*, Item 7.2 (d). This norm will not apply in relation to part of the undertaking or fund of commerce which the licence participates.
[179]*Ibid.*, Item 7.2 (e).
[180]*Ibid.*, Item 7.2 (f). In this case, the administrative authority shall have the power to review, after it has been required to do so, whether or not the circumstances still exist.
[181]*Ibid.*, Item 7.2 (g).
[182]*Ibid.*, Item 7.2 (i).
[183]*Ibid.*, Item 7.2 (h).
[184]See, *e.g.*, **Douglas Gabriel Domingues**, note 17, *supra*, p. 264.

used by developing countries against the behaviour of the developed countries' patent owners, when exercising their rights in the developing countries. Developing countries, on the other hand, see the mechanism of compulsory licence as a way to empower the government with some degree of control over the practice of intellectual property owners. By using compulsory licences, governments can limit the application of the exercise of IPRs by providing some conditions in which this licence may be used in a broader way. On the other hand, as emphasised by Douglas Gabriel Domingues, it is not clear how relevant such a mechanism is. It does not seem to be used as often as intended. This seems to occur as a consequence of other legal tools under which governments have to impose restrictions and limit the practice of intellectual property owners. This discussion, however, must not lead one to think that such legal mechanism is absolutely unnecessary, in so far as it has endured throughout several revisions of national and international laws. Some applicability may be found and some reasons exist to justify the existence of compulsory licences as part of national and international intellectual property laws.

4. TERM OF PROTECTION

The duration of the privilege conferred by a patent is also of importance. While an exclusive monopoly is granted to the patent holder, this exists only for a period of time designed to allow the inventor to exploit his patented product and be rewarded for the investments and efforts which have led to the invention itself.

The Paris Convention is silent in this regard[185] and the PLT negotiations have not agreed if it would follow the example of the Paris Convention or whether a term of protection of at least twenty years should be included in its text[186]. During the negotiations towards the PLT, developing countries clearly stated that the "... term of protection was not justified as there was a serious disparity at the development level between the developed and developing countries. Therefore, duration of patent protection should be left to national laws"[187]. On the other hand, industrialised nations, wishing to include a minimum term of protection, emphasised that "... it was essential that the Treaty include a provision requiring 'an adequate patent term'" as related with "[o]ne of the most important and essential features of the patent system [which] was that it be capable of providing an adequate reward for investment in research and development"[188].

Article 33 of the TRIPS Agreement says that Members of the WTO Agreement shall protect patents for at least twenty years counted from the filing date. Such a provision does not define a maximum term of protection. Members may grant a longer protection for patents without breaching TRIPS rules.

During the negotiations towards the conclusion of the TRIPS Agreement the term of protection for patents was an issue which raised some controversy. While

---

[185]The Paris Convention refers to the duration of protection of patents only in relation with patents obtained for the same invention in different countries when it rules, in Article 4*bis* (5) that "[p]atents obtained with the benefit of priority shall, in the various countries of the [Paris] Union, have a duration equal to that which they would have, had they been applied for or granted without the benefit of priority".

[186]PLT, Art. 22. There are two alternatives: one proposes that no rule on the term of protection of patents should exist (Alternative A) and the other proposes that the minimum duration of a patent shall be for twenty years (Alternative B).

[187]PLT I Conf. Rec., para. 114.12. The Chinese government, however, opposed to the position of developing nations by stating that they were revising their national industrial property law in order to include, *inter alia*, a term of protection of twenty years, thus agreeing with the proposal of Alternative B.

industrialised nations proposed a minimum of twenty years for the duration of a patent[189], developing countries suggested that Members of the WTO Agreement should have the right to establish a term of protection in accordance with their national interests and policies and, consequently, no minimum term of protection should be fixed by the TRIPS Agreement[190].

In Brazil, the CPI says that the privilege granted for a patent shall last for fifteen years from the filing date and will become part of the public domain after it has expired[191]. Law 9279/96, on the other hand, establishes that a patent shall last for twenty years from the filing date and this duration shall not be less than ten years from the date that the patent was granted.[192]

National laws of the States Parties to the MERCOSUL provide for a term of fifteen years of protection, counted from the filing date[193]. On the other hand, both the WIPO Proposal[194] and the Brazilian Proposal[195] suggest a term of protection of at least twenty years counting from the filing date. It seems that no further divergence will result from current negotiations to harmonise patent law in the MERCOSUL, for

---

[188]*Ibid.*, para. 116.10.

[189]See, *e.g.*, proposals of the United States, Switzerland, Canada, Austria, Japan and the European Communities, in GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, pp. 90 and 91. Switzerland, Austria and Japan, for instance, proposed that some provisions should be included on the extension of the duration of a patent which is initially prevented from being launched on the market because of regulatory approval procedures, in particular for pharmaceutical products. See, also, discussion on a supplementary term of protection provided for pharmaceutical products in the context of the European Community, as described in Chapter 4, Section 3, Sub-section 3.3, Paragraph 3.3.1, *supra*.

[190]See, *e.g.*, for the suggestions of Peru, Brazil and India, GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, pp. 90 and 91. India even proposed that a provision allowing developing countries "... to set a shorter duration of patents in sectors of critical importance, such as the food, pharmaceutical and chemical sectors, ..." should be available. Some countries, such as Australia and New Zeland proposed that a minimum term of protection for patents should be of fifteen and sixteen years, respectively (*Ibid.*).

[191]CPI, Art. 24.

[192]Law 9279/96, Art. 40.

[193]**MRE**, note 45, *supra*, p. 10.

[194]In Art. 9.

this aspect of patent protection. It seems that, bound by their international commitments and following international trends in this field of patent protection, States Parties of the MERCOSUL have decided to put forward instruments of harmonisation that would not raise further controversy in relation to the term of protection for patents.

PART 2: PATENTABLE SUBJECT-MATTER

The development of new technologies, together with the needs of modern society, have brought the issues on intellectual property protection forward. The discussion on the protectability of new technologies has raised new issues which have, in turn, brought up new legal discussions and controversy.

The second part of this Chapter studies issues about the patentability of pharmaceutical products and processes, biotechnology and plant varieties. In my opinion these issues will be intimately related to technological and social development in the near future. Technology is an essential tool which will certainly be used further. It is also of particular importance, when considering the degree of technological development of Brazil or of the participating countries of the MERCOSUL. For the drafting of a common science and technology policy for the MERCOSUL the States Parties will have to consider how patent protection in the field of pharmaceuticals, biotechnology and plant varieties should be implemented in accordance with the development needs of the region.

Though there is a major international debate in these fields, until recently there existed no precise instrument obliging nations all over the world to protect such

---

[195] In Item 4.1.

technologies. In the area of pharmaceuticals, for instance, the debate has been recently limited to a struggle between industrialised and technologically rich countries and technologically non-advanced countries. Consequently, the debate on biotechnology and plant varieties protection has followed a similar path.

For the purpose of the present analysis, Part 2 examines the subject on three levels: (1) on the international level, where the issues will be brought from the discussions which have arisen from the conclusion of the Uruguay Round of Negotiations of the GATT and related international agreements under the auspices of the WIPO; (2) a national analysis considers current legislation in Brazil and legislative developments; and (3) at supra-national level, national laws of Argentina, Brazil, Paraguay and Uruguay, and diplomatic negotiating efforts towards a harmonised system of patent protection are considered.

1. PHARMACEUTICAL PRODUCTS AND PROCESSES

Pharmaceutical industries compete on sales world-wide mainly by the development and discovery of new drugs. The Research and Development (R&D) activity of pharmaceutical undertakings is carried out with an enormous amount of financial investment and time[196]. Although only a small fraction of R&D investments become commercially valuable medical products, these few products may gain markets which would give pharmaceutical companies a return for the financial resources they have

[196]It is estimated that the cost of developing a new drug is between 100 and 200 million US dollars, during a period of about 8 to 12 years, until the drug is put into the market. See, for suggested figures, **Commission of the European Communities**, Panorama of EC Industry 1991-1992, Luxembourg: Office for Official Publications of the European Communities (1991), pp. 8-53.

invested in drugs that failed commercially. Pharmaceutical companies are one of the world's most profitable industries[197].

Patent protection is claimed to be the most effective existing mechanism to reward pharmaceutical companies for their creative effort and the high risk they have taken. Gaumont says that "[i]n the economic field, and particularly in the research and development sector, the law is a tool which must permit a better accomplishment of the economic objectives. It is in this spirit that patent, in its modern concept, aims at encouraging the investments necessary for the research and development of the invention ..."[198]. In giving a temporary exclusive right for the exploitation of the invention, therefore, a patent stimulates investments in pharmaceutical R&D and makes those investments possible. Moreover, at the same time that patent prevents other competitors in the pharmaceutical sector from manufacturing, selling or distributing the invention without the owner's consent, it discloses a basic knowledge which is of great relevance to encourage others to invest in further research and improvement of the existing techniques.[199]

Arguments in favour of patent protection for pharmaceutical products and processes claim that legal protection of pharmaceutical innovations allows companies to be rewarded for the high risk investment, permitting further financial resources to

---

[197] See, *e.g.*, **Daniel Green**, European Companies Take on the World, *Financial Times*, 20 January 1995, FT500, p. 39, who says that "[s]even of the top 30 companies in this year's FT500 are pharmaceutical manufacturers, compared with five last year". **Maxwell Gordon**, also, in Licensing's Impact in Pharmaceuticals, [1991] 4 *les Nouvelles* 160-165, p. 161, says that MERCK (one of the largest pharmaceutical industry) has more than one billion dollars in sales derived solely from licensed products, "... but it represents only 15% of the total company pharmaceutical sales".

[198] **Robert Gaumont**, Patentability and Patent Scope of Pharmaceutical Inventions, [1982] 13 *IIC* 431-458, p. 455.

[199] *Ibid.*

be provided for research into new products. Also, the inflow of foreign capital and of relevant technologies will benefit the host country.[200]

Conversely, arguments against the protection of pharmaceutical products and processes claim that patents promote monopolistic behaviour, thus affecting prices and competition; and that patents do not promote the transfer of relevant technology nor encourage pharmaceutical innovation in the host country.[201]

Economic studies have tried to prove that arguments in favour of patent protection have a scientific back up. In particular, Mansfield[202] has suggested *inter alia* that high social returns will happen for the country in which patent protection is granted (including economic and technological development) and that new drugs would not have been introduced to the market, or even developed, in the absence of a patent-like system of protection[203]. Nogués[204] and Challú[205] have studied Mansfield's analysis and concluded, in general, that his conclusions are not based on empirical research and do not prove the arguments in favour of patent protection.

Challú's study, opposing the arguments in favour of patent protection for pharmaceuticals, is summed up by the author as follows:

> 1. No developing countries with product patent laws have succeeded in inventing new drugs; on the contrary, successful results are associated with developing countries without patent systems.

---

[200]**Tom Helter**, Poor Health, Rich Profits: Multinational Drug Companies and the Third World, Nottingham: Spokesman Books (1977), p. 13.
[201]**W. Duncan Reekie**, The Economics of the Pharmaceutical Industry, London and Basingstoke: The MacMillan Press Ltd. (1975), p. 86.
[202]**Edwin Mansfield**, Patents and Innovations: An Empirical Study, *Management Science*, February 1986, *apud* **Julio Nogués**, Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries, [1990] 6 *JWT* 81-103.
[203]**Edwin Mansfield**, , *supra*, pp. 84 and 87, respectively.
[204]**Julio Nogués**, note 202, *supra*.
[205]**Pablo Challú**, The Consequences of Pharmaceutical Product Patenting, [1991] 2 *World Competition* 65-126.

> 2. The hypothesis that a product patent system is able to encourage pharmaceutical invention is not empirically supported. More precisely, it is seen that these two attributes are dissociated, with no relation to each other.
> 3. The analysis of the data shows a close association between a country's degree of economic development and its inventive success in the pharmaceutical field[206].
> 4. The hypothesis that the number of pharmaceutical inventions will increase along with the expansion of patent protection is contradicted by empirical evidence, and must be considered false. The study shows that the extent of world patent coverage and the number of inventions are unrelated. ... In addition, evidence suggests that there is little probability that a medium income or developing country can succeed in inventing new drugs simply by establishing a product patent system.[207]

Although there are some economic studies, such as Mansfield's one[208], attempting to show a close link between expenditure on R&D by pharmaceutical companies and patent protection - being possible to affirm that such discussion influenced the governments of the EC, Japan and the US to introduce some sort of term restoration for patents due to time lost in getting marketing approval -, the present research attempts to avoid the economic discussion about patent protection for pharmaceuticals and tries to focus on the modern legal and political descriptive analysis of the issue.

Additionally, other studies have attempted to describe the impact of multinational drug corporations on consumers in Latin American, or developing countries in general. Among the practices in these countries, there is evidence of

---

[206]Challú himself has affirmed that most countries have adopted patent protection for pharmaceutical products after having reached a high degree of economic development, where the major exception is the US. In addition, Challú says that US pharmaceutical industries have benefited from the US government's policy of blocking German drugs during World War I and further stimulus has arisen from World War II, where high government demand for drugs to combat infections disease took place (**Pablo Challú**, note 205, *supra*, pp. 74-75).
[207]**Pablo Challú**, note 205, *supra*, pp. 87-88.
[208]Note 202, *supra*.

bribery, high-price policy and costly advertising campaigns for selling drugs which have not been approved by the US Food and Drug Administration (FDA)[209].[210]

1.1. International legislation: the TRIPS Agreement

One of the most important and controversial issues of the negotiations during the Uruguay Round was the patentability of pharmaceutical products and processes. Current international industrial property laws, in particular the Paris Convention, do not oblige countries to grant such patents.

The US, Japan and the European Community insistently stressed that the lack of patentability for pharmaceutical products, in particular,[211] was wrong and that the negotiations in GATT should address the matter more effectively.[212] Some other countries also suggested that the obligation to protect pharmaceutical products should be made explicit in the text of the TRIPS Agreement[213].

---

[209]The FDA is a US governmental body which controls and approves the market of drugs and foodstuff. The FDA takes into account, among others, human and animal health, biosafety measures, and environmental-related issues.

[210]See, in general, **Robert J. Ledogar**, Hungry for Profits: US Food and Drug Multinationals in Latin America, New York: IDOC/North America, Inc. (1975); **Jonathan L. Mezrich**, The Patentability and Patent Term Protection of Lifesaving Drugs: A Deadly Mistake, [1992] 2 *Journal of the Patent and Trademark Office Society* 77-95; and **Tom Helter**, note 200, *supra*.

[211]The protection of processes for the production of pharmaceutical products was not considered the main issue. Industrialised nations argued that some countries provided for the protection of pharmaceutical processes, but it was not satisfactory. There was also a need to protect the final product, as a result of a protected process. See, *e.g.*, GATT Doc. N. MTN.GNG/NG11/W/7 (29 May 1987) Submissions from Participants on Trade Problems Encountered in Connection with Intellectual Property Rights, p. 3, for the opinion of the EC; p. 8, for Japan, and; p. 24 for the position of the US.

[212]*Ibid.*. The EC has also addressed the issue on compulsory licensing of pharmaceutical products (at p. 4), while the United States has expressed worries in which regards to the term of protection for pharmaceutical products, as generally not satisfactory, because of the testing and approval requirements (at p. 25).

[213]See submissions by Austria and Republic of Korea in GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, at pp. 86 and 87, respectively.

Developing countries were strongly against the inclusion of an obligation to protect pharmaceutical products and processes in the TRIPS Agreement.[214] India particularly opposed the protection of pharmaceuticals, arguing that it would have "... adverse implications for the growth of indigenous industry as well as research and development efforts", and that it would result "... in higher price of medicine for the common man"[215].

A group of developing countries also proposed, in a more flexible way, that Members of the TRIPS Agreement should be allowed to exclude from patentability, "... on grounds of public interest, national security, public health or nutrition, certain kinds of products or processes for the manufacture of those products ...", in so far as the national treatment principle would be respected.[216] This proposed provision suggested that a possibility would be given to Members to exclude pharmaceutical products and processes from patent protection.

Members, at the end of the day, are to protect pharmaceutical products and processes. The final agreement concluded in Marrakesh, in April 1994, established that "... patents shall be available for any inventions, whether products or processes, in all fields of technology ..."[217]. Members may exclude from patentability, however, "diagnostic, therapeutic and surgical methods for the treatment of humans and animals"[218]. Although it was not expressly mentioned, the wording of the TRIPS

---

[214]See, in particular, the submissions by India and Peru, in GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, at p. 85.
[215]GATT Doc. N. MTN.TNC/MIN(90)/ST/46 (4 December 1990) India: Statement by Dr. Subramanian Swamy, Union Minister of Commerce, Law and Justice, p. 4.
[216]GATT Doc. N. MTN.GNG/NG11/W/71 (14 May 1990), Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, p. 8, Article 4 (2).
[217]TRIPS Agreement, Art. 27 (1).
[218]*Ibid.*, Art. 27 (3) (a).

Agreement does not give any possibility for Members to exclude pharmaceutical products and processes from patent protection. It merely allows them to exclude methods (diagnostic, therapeutic and surgical) for the treatment of humans or animals.

A more detailed analysis on the patentability of pharmaceuticals within TRIPS is not concluded yet. At least two other issues may be included in the discussion.

Firstly, it must be said that at least the US, Switzerland and Japan believed that a further term of protection for pharmaceutical products should be encouraged by the TRIPS Agreement.[219] Developing countries, namely India, suggested, on the other hand, that Members should be permitted to set a shorter term of protection for sectors of critical importance, such as the food, pharmaceutical and chemical sectors[220].

Developed countries have strongly argued that pharmaceutical products suffered from marketing delays due to "regulatory approval procedures"[221] as required by governments. The "patent term restoration" for pharmaceuticals, provided for instance by the EC[222], is a subject which has been brought to the TRIPS negotiations by the interests of those countries where such industries are strategic economic sectors.

The Agreement on TRIPS finally provided that Members are free to determine longer terms of protection for pharmaceutical products, but there is neither explicit encouragement nor any obligation to do so. Article 33 of the TRIPS Agreement says

---

[219]GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, at pp. 90 and 91.
[220]*Ibid.*, p. 91.
[221]In connection with the "regulatory approval procedures" required for the marketing of pharmaceutical and agricultural chemical products, Article 39 (3) of the TRIPS Agreement establishes that "the submission of undisclosed test or other data" shall be protected by the government in question against unfair commercial use and against disclosure, except where necessary to protect the public.
[222]*Cf.* Chapter 4, Section 3, Sub-section 3.3, Paragraph 3.3.1, *supra*.

only that Members shall protect patents, in general, for at least twenty years counted from the filing date.

Another issue discussed during the TRIPS negotiations, as proposed by the US, that provisional protection should be provided for "...products embodying subject matter deemed to be unpatentable under its [*i.e.* a Member's] patent law prior to its acceptance to this Annex [the TRIPS Agreement], ..."[223] raised more controversy, particularly, in the negotiations towards the implementation of the TRIPS Agreement in the Brazilian Parliament[224]. The so-called "pipeline" protection should be made available if the subject matter to which the product relates will become patentable after the acceptance of the TRIPS Agreement[225], or if a patent has been issued for the product in question by another Member of the WTO Agreement[226], and the product has not been marketed and/or commercialised in the territory of the Member providing the transitional protection for that specific product[227].

Considered as an isolated initiative of the US, the proposed "pipeline" protection has been finally included in the TRIPS Agreement. Although Article 70 (1), TRIPS Agreement, creates the general rule that the TRIPS Agreement does not "... give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question", Article 70 (8) and (9) of the TRIPS Agreement has provided for an exception to the general rule.

Article 70 (8), TRIPS Agreement, states that where a Member does not make available patent protection for pharmaceutical and agrochemical products as of the

---

[223]GATT Doc. N. MTN.GNG/NG11/W/70 (11 May 1990) Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights, Communication from the United States, at p. 10, Art. 26.
[224]See further aspects of the Parliamentary negotiations in Brazil in Sub-section 1.2, *infra*.
[225]GATT Doc. N. MTN.GNG/NG11/W/70, note 223, *supra*, Art. 26 (1).
[226]*Ibid.*, Art. 26 (2).

date of entry into effect of the WTO Agreement, such a Member must provide a means by which applications for such patents may be filed[228]. Further, Article 70 (8) (b), TRIPS Agreement, determines that the date of the application of the provisions on the criteria for patentability as established by the Agreement on TRIPS, applies to these applications "... as if those criteria were being applied on the date of filing in that Member ..." and that "..., where priority is available and claimed, the priority date of the application" will apply[229].

It is noteworthy that Members are not obliged to grant patents for such products before the entering into force of the TRIPS Agreement in that Member of the WTO Agreement, taking into account the transitional period provided in Part VI of the TRIPS Agreement. Nevertheless, when patents are granted after the Agreement is effectively applicable in that particular Member, the protection will last for the twenty year term counted from the filing date, as provided by Article 33 of the TRIPS Agreement, and for the remainder of the patent term, for those applications which fulfil the conditions for patentability as laid down by the TRIPS Agreement.[230]

Further, pursuant to paragraph (9) of Article 70, TRIPS Agreement, Members shall grant "exclusive marketing rights" for a period of five years, after the marketing approval procedures have taken place, for those applications which have fulfilled the conditions for patentability of the TRIPS Agreement. Those rights will no longer be

---

[227] *Ibid.*, Art. 26 (3).
[228] TRIPS Agreement, Article 70 (8) (a).
[229] According to **Carlos Correa**, note 124, *supra*, at p. 335, Article 70 (8) (b) "... preserves, ..., the novelty of the application through a legal fiction based on the assessment of novelty (and other criteria for patentability) as if it were [sic] judged on the date of the filing of the application ... and not when evaluation actually takes place".
[230] TRIPS Agreement, Article 70 (8) (c).

available if the patent is finally granted or if the patent application is rejected in that Member of the WTO Agreement, whichever period is shorter.

Carlos Correa[231] alerts us to the lack of detail regarding the scope and application of the term "exclusive marketing rights" as used in the TRIPS Agreement, and poses further questions relating to the type of remedies against infringements which will be available to the right holder, the application of compulsory licensing procedures against those rights, and the extent to which acts would be permitted for third parties that wish to use the invention for experimentation, tests, manufacture or market approval. However, it is possible to argue that such a detailed analysis of complex questions should be dealt with by national laws. The scope of the TRIPS Agreement is limited to setting up general principles and standards for intellectual property protection. It is not, as one might think, a "model law" imposed on its Members. Members shall, however, comply with these principles and general rules according to Article 65 of the TRIPS Agreement.

1.2. The legislation in Brazil

Pharmaceutical processes and products were protected in Brazil from the 1930s until 1945, when Decree-Law N. 7.903, of 27 August 1945, came into effect. Past legislation provided for the protection of both pharmaceutical products and processes. Decree-Law N. 7.903/45, in Article 8 (2), excluded from protection inventions which have as a subject matter substances or food products and medicine of any type. Article 8, Sole paragraph, nevertheless says that such exclusion would not apply to new processes destined for the manufacturing of such substances or products.

This situation was changed only in 1969, when the Decree N. 1.005, of 21 October 1969, in Article 8 (b) and (c) respectively, widened the principle established by the 1945 legislation, and excluded both pharmaceutical products and processes from patent protection. The CPI has also provided that neither pharmaceutical products nor processes enjoy patent protection[232].

Motivated by the developments of Brazilian international commitments and the wish to harmonise Brazilian legislation with international practice[233], as well as responding to the constant pressure from the US[234], the patentability of pharmaceutical products and processes has been one of the most controversial issues during the parliamentary negotiations of Law 9279/96.

---

[231]Note 124, p. 335.

[232]CPI, Art. 9 (c).

[233]Mensagem Presidencial N. 192, of 30 April 1991.

[234]Since 1985 until the approval of Law 9279/96, the US has insistently threatened Brazilian products with unilateral sanctions due to the lack or insufficient protection of IPRs, in particular pharmaceutical products. On 7 September 1985, the US President announced the initiation of investigations under Section 301 of the Trade and Tariff Act of 1984, against Brazilian policy on the restrictions to computer technology products. On 11 June 1987, the US Pharmaceutical Manufacturers Association (PMA) filed a petition before the US government requesting unilateral commercial sanctions against Brazil, on grounds of "unreasonable" protection of pharmaceutical products. A few months later, on 20 October 1988, President Reagan declared that, under Section 301 of the "Omnibus Trade and Competitiveness Act of 1988", in ten days 100% *ad valorem* tariffs would be imposed against some Brazilian paper, chemical and electronic products. The Brazilian government requested a Panel in the GATT to resolve such a dispute. The unilateral sanctions imposed by the US were eventually withdrawn on 2 July 1990, after Brazilian President Fernando Collor submitted to the Brazilian Parliament a legislative Bill (PL 824/91) proposing broader protection for patents, including pharmaceutical and chemical products, biotechnology, and foodstuffs (the information provided above was borrowed from **Maria Stela Pompeu Brasil Frota**, Proteção de Patentes de Produtos Farmacêuticos: o Caso Brasileiro, Brasília: FUNAG/IPRI (1993), pp. 47-53; and **Maria Helena Tachinardi**, A Guerra das Patents - O Conflito Brasil x EUA sobre Propriedade Intelectual, Rio de Janeiro: Editora Paz e Terra S.A. (1993), pp. 105-112). From 1992 to 1996, however, the US government kept threatening Brazilian products with unilateral sanctions due to the non-approval of the legislative Bill regulating industrial property rights. Information about US threats in this regard was widely disseminated by Brazilian newspapers during this period. For some viewpoints highlighting the contradiction between the US speech and practice in international trade, particularly related to intellectual property protection see, *e.g.*, **Rogério Cezar de Cerqueira Leite**, Patentes e Pressões Norte-Americanas, *Folha de São Paulo*, 5 May 1993, Caderno 2, p. 2, and **Eugênio da Costa e Silva**, Brasil-Estados Unidos e a Propriedade Industrial, *Correio Braziliense*, 4 June 1995, p. 7.

Initially strong opposition against the patentability of pharmaceutical products and processes took place[235], arguing that developing countries do not protect pharmaceutical products and processes in order to ensure access to cheaper medicines to the population and to develop a national pharmaceutical industry[236].

Despite efforts against pharmaceutical protection, the government was carefully dealing with the US dissatisfaction with Brazilian current industrial property law[237]. The protection of pharmaceutical products and processes has been included in all versions of the legislative Bill during the negotiations in the Brazilian parliament[238] and eventually became part of the recently approved Law 9279/96.

There are probably 400 pharmaceutical industries in Brazil with a total turnover of nearly three billion US dollars per year (1990). About 80% of this total

---

[235]Even a Forum, called "Forum pela Liberdade do Uso do Conhecimento", (or Forum for the Freedom of Knowledge Use) was established in 17 February 1992, with the participation of various segments of Brazilian society, including the academic community, the religious community, Brazilian industries, representatives of the Brazilian Bar Association, and others (in **Aldo Rebelo** (ed.), Lei das Patentes e Soberania Nacional, Brasília: Coordenação de Publicações, Câmara dos Deputados (1992)). Although the goals of this informal association was to discuss the proposed industrial property law as a whole, most emphasis was given to the issues on pharmaceutical products and processes and biotechnology.

[236]During the Parliamentary negotiations of Law 9279/96, several arguments were used for and against the protection of pharmaceutical products. The usual argument in favour of pharmaceutical products was that protection would be the incentive for investment in research and development, eventually encouraging the transfer of relevant technology to Brazil and, that Brazil was taking a difficult position in the international arena as a "pirate" of pharmaceutical products. The usual arguments against the protection of pharmaceutical products were that the national pharmaceutical industry has not had time to develop further, and that multinational pharmaceutical corporations would monopolise the market with high prices medicines. For a general survey of the positions of the national and multinational pharmaceutical industries, see **Maria Stela Pompeu Brasil Frota**, note 234, *supra*, pp. 91-96.

[237]*Cf.* note 234, *supra*.

[238]The first version, in the Brazilian Parliament, modifiying the legislative Bill submitted to the National Congress by President Fernando Collor (*i.e.* Mensagem Presidencial N. 192/91, which became "Projeto de Lei" N. 824/91), suggested, however, the exclusion from patent protection of pharmaceutical products which are listed as essentials by the World Health Organization (WHO) (in PL 824-B/91, Article 18 (VI)). This provision was eliminated from the text of the legislative Bill even before it was sent to the Federal Senate. Thus, in PLC 115/93 this provisions was no longer available.

representing the turnover of only fifty foreign industries. The remaining 20% is the turnover of the Brazilian industries, representing less than 1% of the total turnover.[239]

When, in 1969, protection for pharmaceutical products and processes was no longer available in the Brazilian territory, it was expected that Brazilian pharmaceutical industries would develop technologies based on foreign practice. Clearly, the figures quoted in the last paragraph demonstrate that Brazilian national development in the field of pharmaceuticals has not been as expected. One may argue that this is because there was not the necessary scientific and technological policy efforts to build up a strong national pharmaceutical industry. Not only the non-protection of pharmaceutical patents is necessary to develop an industry.

The arguments against the protection of pharmaceuticals are no longer effective. Law 9279/96 contains rules that may be used against the abuse or misuse of the privilege conferred upon a pharmaceutical patent holder. Also, there are laws to regulate market behaviour, prices and competitive activities of different economic sectors in Brazil.[240]

In the pharmaceutical debate, what was a matter of great controversy during all stages of Parliamentary negotiations of the Law 9279/96 was the inclusion of the

---

[239]**Cícero Gontijo, Fernando Antonio Lyrio Silva, Francisco Eugênio Machado Arcanjo & Ronaldo Bayma Archer da Silva**, Contribuição à Compreensão do PLC 115, de 1993, Brasília: Assessoria Legislativa do Senado Federal, *mimeo*, 22 September 1993, p. 21. An interesting fact, to corroborate the argument that patent protection is not necessarily a condition *sine qua non* for encouraging investment in R&D made by foreign undertakings in developing countries, is an advertisement published by AKZO, a Dutch pharmaceutical and chemical corporation, in the back cover of the *Economist* of 13 November 1993, V. 329, which quotes the following declaration from Roberto Schverdfinger, General Manager of Organon Argentina SA: "I'm proud to work for a pharmaceutical company - within Akzo - that invests a large part of its income in R&D. New or improved pharmaceuticals are important to everyone's well-being. But it is of special relevance here in Argentina. Argentinean law does not protect medical patents, so the market is flooded with hundreds of me-too products. Despite this tough competition we have doubled our sales during the last two years".

"pipeline" protection for pharmaceutical and chemical products[241]. Article 230 of the Law 9279/96 states that the foreign holders of rights over pharmaceutical, chemical products and processes and foodstuffs can apply for a patent, in the case of a patent that has not been granted in the country of origin and the subject matter of the claimed patent has not been put into the market, directly by the right holder or by someone else with his consent. Further, it is required that a third party, in Brazil, has not taken effective and serious preparation for the exploitation of the subject matter of that patent. The successful patent applicant will enjoy the privilege for a period which takes into account the filing date and the remaining term of protection that such patent enjoys in the country of origin[242].

Pipeline protection will be also allowed for Brazilian nationals or someone domiciled in the country, subject to the same conditions as applied to foreign applicants.[243] The successful patent, in this case, will enjoy twenty years of protection counted from the filing date[244].

It is also important to note that the pipeline protection, as provided by Law 9279/96, has already been in force since the date of publication of the Law 9279/96[245]. In addition, the Brazilian President is expected to sign a Decree granting exclusive marketing rights for medicines and other products which are not patentable in Brazil, but are registered abroad. It seems that this Decree is a provisional measure which is intended to harmonise Brazilian industrial property laws and procedures with

---

[240]For further reference on regulatory provisions on competition practices, its development and interpretation, in Brazil, see Chapter 6, Section 2, Sub-section 2.2, *infra*.
[241]*Cf.* Paragraph 1.1, *supra*, for the US "pipeline" proposal during TRIPS negotiations.
[242]Law 9279/96, Art. 230 (4).
[243]*Ibid.*, Art. 231.
[244]*Ibid.*, Art. 231 (3).
[245]*Ibid.*, Art. 243.

the country's international commitments, namely the TRIPS Agreement[246]. The INPI, on the other hand, is already discussing a draft internal regulation to discipline the procedural aspects of the pipeline protection[247].

1.3. The negotiations in the MERCOSUL

The legislation of all States Parties, except recently approved Brazilian Law 9279/96, excludes pharmaceutical products from patent protection. Brazil was the only country to exclude also the process for the production of a pharmaceutical product.[248]

The WIPO has suggested, in accordance with the provisions of the TRIPS Agreement, that patents should be granted to all inventions, whether product or process[249]. In the WIPO Proposal, only methods (therapeutical, surgical or diagnostic) for the treatment of humans or animals should not be considered as an invention[250].

The Brazilian Proposal has suggested that States Parties of the MERCOSUL shall grant patents to inventions which fulfil the requirements of novelty, inventive activity and industrial application[251]. Further, the Brazilian Proposal suggests that States Parties may adopt measures to impede or limit the exploitation of patented

---

[246]In *SBPC Hoje* (4 September 1995), N. 393. It is also reported that foreign industries have already filed at least 100 patent applications in the INPI for pharmaceutical products or processes.

[247]Information provided by letter from the President of the INPI, Vanda Scartezini, (OF/INPI/PR/N. 62/96, of 25 April 1996) to the President of ABPI, Juliana Laura Bruna Viegas.

[248]WIPO Doc. N. OMPI/MERCOSUR/MVD/94/2 (March 1994) Reunion de Expertos Gubernamentales sobre Propiedad Intelectual en los Paises Miembros del MERCOSUR, Organizado por la Organización Mundial de la Propiedad Intelectual (OMPI) en Coordinación con el Grupo Mercado Común del MERCOSUR y la Asistencia del Programa de las Naciones Unidas para el Desarrollo (PNUD), p. 9, para. 22, and; **MRE**, note 45, *supra*, pp. 4-5. It is important to note that, recognising the difficulties for the patent owner to prove an infringement on process patents, the TRIPS Agreement determined, in Article 34, that either the defendant or the alleged infringer will be obliged to prove, during civil proceedings, that the process to obtain an identical product is different from the patented process.

[249]WIPO Proposal, Art. 1 (1).

[250]*Ibid.*, Art. 1 (2).

[251]Brazilian Proposal, Item 1.1.

inventions, when necessary to guarantee public order, public morals, including the protection of human, plant or animal health[252]. It is possible that this provision could be considered as leaving to States Parties the possibility of interpreting the common law as, in some cases, impeding or limiting the commercial exploitation of a patented invention. All patented inventions may fall within the limitation considered for the MERCOSUL. That provision shall not be considered when analysing either the issues on compulsory licence or matters related to the exclusions and exceptions of patentable subject-matters. States Parties are only allowed to limit the unsafe commercial exploitation of an invention.

2. *BIOTECHNOLOGY*

A definition of biotechnology has been formulated by the UNIDO/WHO/UNEP Working Group on Biotechnology Safety as "... the application of biological systems and organisms to scientific, industrial, agricultural and environmental processes and uses", where the term "'[o]rganisms' includes plants, animals and microbes that occur naturally or that have been genetically modified"[253].

Also, the Paris Union Committee of Experts on Biotechnological Inventions and Industrial Property, in its First Session, decided that, for the purposes of that specific study, biotechnology should be understood as "..., all technological

---

[252] *Ibid.*, Item 1.3.

[253] UNEP Doc. N. UNEP/Bio.Div.3/Inf.5 (23 May 1990) Biotechnology: Concepts and Issues for Consideration in Preparation of a Framework Legal Instrument for the Conservation of Biological Diversity, p. 3, para. 3. Accordingly, the Convention on Biological Diversity (CBD), 31 *ILM* 818 (1992), defines biotechnology, for the purpose of its application, as "... any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" (CBD, Art. 2).

developments concerning living organisms (which include animals, plants and microorganisms) and other biological material ...".[254]

Although considering the ethical questions related to biotechnological developments in relation with humans, it was decided that such study at WIPO would cover all living organisms and the term "animals" should include non-humans and human beings. The WIPO study, nevertheless, would not consider in detail questions on the patentability of inventions relating to human beings.[255]

A further analysis of the concept of biotechnology may be divided in two ways. For thousands of years, man has used "traditional biotechnology", which includes *inter alia* the basic fermentation techniques, methods of selective breeding and cross-breeding of plants and animals (mostly cattle) and the production of serum and vaccines for human or animal health. The evolution of human knowledge, in general, and the developments of new technologies have brought research to very sophisticated levels.

"Modern biotechnology" is probably the technology which will have greatest strategic importance for the drawing up of national science and technology, and industrial policies. Such a technology was only possible with the advance of knowledge regarding genetic and molecular structures. Its concepts include techniques of genetic engineering and other technologies derived from cellular and molecular biology, and the production of transgenic plants or animals.[256]

---

[254]WIPO Doc. N. BioT/CE/I/3 (9 November 1984) Committee of Experts on Biotechnological Inventions and Industrial Property, First Session, Geneva, November 5 to 9, 1984, at p. 7, para. 22.

[255]*Ibid.*, p. 7, para. 25.

[256]See, generally, **Cícero Gontijo** *et al.*, note 239, *supra*, p. 25, and **Willian Antonio Cerantola** Estratégias Tecnológicas das Empresas de Biotecnologia no Brasil, [1992] 2 *Revista de Administração* 5-14, p. 7.

The results of biotechnological processes are widely applicable. Biotechnology can be used in several economic and technological sectors, such as agriculture, cattle breeding, cattle raising, chemistry, energy, environment, foodstuffs, mining, and pharmaceuticals. Particular areas which seem to obtain larger economic advantages from biotechnology R&D activities are health and agriculture. The issues about pharmaceutical[257] and plant varieties[258] protection are closely linked with the issues on the protectability of biotechnology.

Within the conceptual discussion on the legal protection for biotechnological processes and products, environmental law also plays a very important role in modern discussion. The inclusion of environmental discussion in the biotechnological debate was formally established after the commitments reached at the UNCED in 1992.[259]

Several aspects of "biodiversity prospecting" are worth considering, as well as its relationship with modern discussion of IPRs. Below, Chapter 7, which is added as a complementary discussion to the present analysis, studies the issues further aiming to propose a link between the provisions of the CBD and this research.

2.1. International legislation

On the international level, there are legal instruments established to protect biotechnological inventions. They are the International Convention for the Protection of New Varieties of Plants[260], which is the first international agreement set up to protect biotechnology and which will be analysed in Section 3, *infra*; and the

---

[257]Considered in more detail in Section 1, *supra*.
[258]Considered in more detail in Section 3, *infra*.
[259]Particularly the issues as in the CBD.

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure[261], established in 1977 to set up a system for the transmission and/or storage of micro-organisms to an international depositary authority, for the purposes of patent applications. The TRIPS Agreement also sets up mandatory obligations regarding the protection of inventions in the field of biotechnology.

2.1.1. The Budapest Treaty

A depositary mechanism for patent purposes is regarded as necessary "... partly to guarantee the existence of the microorganisms and partly to supplement the description, ..."[262] in so far as the disclosure of the patent, as well as the conditions of novelty, inventive step and industrial applicability, can be effectively assessed.

Apparently, there are still some doubts regarding the assessment of the conditions of sufficient disclosure, in connection with the requirement of repeatability which may be considered in the following way:

> ... the disclosure ha[s] to enable an average expert to arrive at the same, or at least largely the same, result as the inventor. Repeatability did not only exist, if the disclosure consisted of a full description, but also, if, in the case of a microorganism, the major part of the disclosure was in the form of a deposit of the microorganism.[263]

---

[260]Known as the "UPOV Convention" and done on 2 December 1961, being revised at Geneva on 10 November 1972, 23 October 1978 and 19 March 1991 (Geneva: International Union for the Protection of New Varieties of Plants (1992)).

[261]Known as the "Budapest Treaty", done at Budapest on 28 April 1977 and amended on 26 September 1980 (published with the Regulations, Geneva: WIPO (1989)).

[262]WIPO Doc. N. BioT/CE/I/3 (9 November 1984) Committee of Experts on Biotechnological Inventions and Industrial Property, First Session, Geneva, November 5 to 9, 1984, p. 16, para. 70.

[263]WIPO Doc. N. BioT/CE/II/3 (7 February 1986) Committee of Experts on Biotechnological Inventions and Industrial Property, Second Session, Geneva, February 3 to 7, 1986, p. 14, para. 70.

For the purposes of depositary procedures, the Budapest Treaty establishes that a depositary institution, which has acquired the status of an international depositary authority[264], will provide for the receipt, acceptance and storage of the micro-organism and the furnishing of samples.[265]

Rule 2.1 of the Regulations of the Budapest Treaty says that an international depositary authority may be a government agency, a public government body related to a public institution, or a private entity, in so far as such an authority has staff and facilities able "... to store the deposited microorganisms in a manner which ensures that they are kept viable and uncontaminated"[266], and that sufficient safety measures are taken to minimise the risk of losing deposited micro-organisms[267].

The international depositary authority shall accept any kind or certain kinds of micro-organisms[268] and be available, for the purposes of deposit, to any depositor[269] under the same conditions[270], being impartial and objective in its procedures[271].

The international depositary authority shall also refuse to accept the micro-organism, notifying the depositor of such refusal and the reasons for that decision[272], where the authority is technically not in a position to perform the tasks established by

---

[264]To qualify for the status of an international depositary authority, a depositary institution must be located in the territory of a Contracting State of the Budapest Treaty and must benefit from guarantees provided by the State in question that the said institution complies (Budapest Treaty, Art. 6 (1)) with the requirements which will be discussed further in this Paragraph.
[265]Budapest Treaty, Art. 2 (vii) and (viii).
[266]Regulations of the Budapest Treaty, Rule 2.2 (i).
[267]*Ibid.*, Rule 2.2 (ii).
[268]Budapest Treaty, Art. 6 (2) (v).
[269]"'[D]epositor' means the natural person or legal entity transmitting a microorganims to an international depositary authority, which receives and accepts it", and any successor in title of the said natural or legal entity (Budapest Treaty, Art. 2 (iv)).
[270]Budapest Treaty, Art. 6 (2) (iv).
[271]*Ibid.*, Art. 6 (2) (iii).
[272]Regulations of the Budapest Treaty, Rule 6.4 (a).

the Treaty, because of the exceptional properties of the micro-organism[273], and where the micro-organism is supplied on conditions that indicate that the micro-organism is missing or which for scientific reasons preclude the acceptance of the micro-organism[274]. Any international depositary authority may require that the micro-organism be deposited in the form and quantity necessary for the purposes of the Budapest Treaty[275].

The depositary authority must also issue to the depositor, in respect of each deposit of micro-organism, a receipt confirming the fact that it has received and accepted the micro-organism for deposit purposes[276]. The authority shall also test the viability of each micro-organism which has been deposited before it[277], and shall issue a statement concerning its viability[278].

In its capacity as international depositary authority, the depositary institution shall store the micro-organism for a period of at least five years after the most recent request for the furnishing of a sample was received, and, in any case, for a period of at least thirty years counted from the date of the deposit.[279]

The depositary authority may provide samples to interested industrial property offices, for the purpose of patent procedures related to the micro-organism[280]. It may also furnish samples to the depositor on his request or, with the authorisation of the depositor, to any authority, natural person or legal entity at the request of such

---

[273]*Ibid.*, Rule 6.4 (a) (ii).
[274]*Ibid.*, Rule 6.4 (a) (iii).
[275]*Ibid.*, Rule 6.3 (a) (i).
[276]Budapest Treaty, Art. 6 (1) (vi), and Regulation of the Budapest Treaty, Rule 7.1.
[277]Regulations of the Budapest Treaty, Rule 10.1.
[278]Budapest Treaty, Art. 6 (1) (vi), and Regulations of the Budapest Treaty, Rule 10.2.
[279]Regulations of the Budapest Treaty, Rule 9.1.
[280]Budapest Treaty, Art. 6 (viii), and Regulations of the Budapest Treaty, Rule 11.1.

party[281].[282] Depositary authorities shall not, except under the foregoing circumstances, give any information to anyone concerning any micro-organism deposited with it under the Budapest Treaty[283].

The depositor must supply the depositary authority with a written statement bearing his signature and containing the details of the conditions necessary for the cultivation, storage and testing of the viability of the micro-organism[284], and shall indicate the properties of the micro-organism which are or may be dangerous to health or to the environment[285]. The depositor must also provide the depositary authority with his name and address[286], must indicate that the deposit is made under the Budapest Treaty, giving a guarantee that the deposit will not be withdrawn for at least thirty years[287]. The depositor must also give an identification (numbers, symbols, etc.) to the micro-organism[288]. It is strongly recommended that the depositor includes in the written statement "... the scientific description and/or proposed taxonomic designation of the deposited microorganism"[289].[290] If any of these conditions are not

---

[281] *Ibid.*, Art. 6 (viii), and Regulations of the Budapest Treaty, Rule 11.2.

[282] Under certain conditions, established by Rule 11.3 of the Regulations of the Budapest Treaty, an international depositary authority shall also furnish samples of a deposited micro-organism to parties legally entitled to it. However, discussions have taken into consideration that samples of a deposited micro-organism should be made generally available to the public upon request (WIPO Doc. N. BioT/CE/III/3 (3 July 1987) Committee of Experts on Biotechnological Inventions and Industrial Property, Third Session, Geneva, June 29 to July 3, 1987, pp. 25 to 29, paras. 114-144).

[283] Budapest Treaty, Art. 6 (vii), and Regulations of the Budapest Treaty, Rule 9.2.

[284] Regulations of the Budapest Treaty, Rule 6.1 (a) (iii).

[285] *Ibid.*, Rule 6.1 (a) (v).

[286] *Ibid.*, Rule 6.1 (a) (ii).

[287] *Ibid.*, Rule 6.1 (a) (i).

[288] *Ibid.*, Rule 6.1 (a) (iv).

[289] *Ibid.*, Rule 6.1 (b).

[290] These are the requirements regarding "original deposits". The requirements for "new deposits" are almost the same but in addition the depositor must state the relevant reasons for making a new deposit and must affirm that the micro-organism is the same (Implementing Regulations of the Budapest Treaty, Rule 6.2 (a) (ii)). He shall also provide the most recent scientific description and/or taxonomic designation of the micro-organism, if the same was provided for the original deposit (*Ibid.*, Rule 6.2 (a) (iii))

met, the depositary authority shall notify the depositor immediately and invite him to comply with the missing requirements[291].

As a final point, it is important to note that, in the light of the provisions of the Budapest Treaty, no definition of a micro-organism exists. During the Diplomatic Conference on the Budapest Treaty, it was agreed not to adopt a provision defining micro-organisms, leaving the question to the depositary authorities, who are free to accept deposits of everything they consider a micro-organism, under the terms established by the Budapest Treaty.[292]

It is also worth mentioning that, as at 1 January 1996, most European countries (*i.e.* Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Liechtenstein, the Netherlands, Norway, Poland, Russian Federation, Spain, Sweden and the UK) as well as Japan and the US are Contracting Parties to the Budapest Treaty. On the other hand, no States Party of the MERCOSUL is Contracting Party to the Budapest Treaty.[293]

2.1.2. The TRIPS Agreement

Biotechnology was also a major issue in the TRIPS negotiations. Developed countries, in general, suggested that biotechnological inventions should be protected more widely under the patent system[294]. The US argument was that the two existing

---

[291]Regulations of the Budapest Treaty, Rule 6.4 (b).

[292]WIPO Doc. N. BioT/CE/I/3 (9 November 1984) Committee of Experts on Biotechnological Inventions and Industrial Property, First Session, Geneva, November 5 to 9, 1984, p. 21, para. 100.

[293]WIPO Doc. N. 423 (E) (1 January 1996) States Party to the Convention Establishing the World Intellectual Property Organization (WIPO and/or the Other Treaties Administered by WIPO and/or to the International Convention for the Protection of New Varieties of Plants (UPOV) - Governing Bodies of WIPO, of the Unions Administered by WIPO and their (Permanent) Committees, and of the Rome Convention, p. 22

[294]See, generally, GATT Doc. N. MTN.GNG/NG11/W/7, note 211, *supra*, at pp. 29 and 30 (opinion of the US), GATT Doc. N. MTN.GNG/NG11/W/12/Rev.1 (3 February 1988) Compilation of Written

international conventions dealing with biotechnology protection matters - the Budapest Treaty and the UPOV Convention - were not widely adhered to[295], causing a lack of harmonisation on national laws on this matter, or even the absence of any protection at all[296].

Some other industrialised nations suggested more limited ways of protecting biotechnology. The EC, for instance, recommended, in accordance with the provisions of the EPC, that Members of the WTO Agreement should be allowed to exclude from patentability plant or animal varieties or essentially biological processes for the production of plants and animals, excluding microbiological processes or products and plant varieties[297].

Developing countries proposed that plant or animal varieties or essentially biological processes for the production of plants or animals should be excluded from patent protection altogether.[298] Understanding that biotechnology is such a new and complex subject, with effect on several influential sectors of national economies,

---

Submissions and Oral Statements, at p. 14, para. 41 and GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, at p. 86 (the suggestion of Austria) and p. 87 (the suggestion of Republic of Korea).

[295]GATT Doc. N. MTN.GNG/NG11/W/7, note 211, *supra*, p. 30.

[296]See, generally, GATT Doc. N. MTN.GNG/NG11/W/24/Rev.1 (15 September 1988) Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Note Prepared by the International Bureau of WIPO, Annex II, p. 96 points (ii) and (iv) and p. 97, point (v).

[297]GATT Doc. N. MTN.GNG/NG11/W/68 (29 March 1990) Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, p. 10, Art. 23 (2) and (3). Note, however, that in the first place the EC suggested that patents should not be available at all to plant or animal varieties or essentially biological processes for the production of plants or animals, excluding microbiological processes or the products thereof (GATT Doc. N. MTN.GNG/NG11/W/26 (7 July 1988) Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights, p. 6). It is also worth considering that the Nordic countries did not urge "... broad patent coverage without exclusions for plants and living organisms", as stated by **Julie Chasen Ross & Jessica A. Wasserman**, Trade-Related Aspects of Intellectual Property Rights, p. 50, point 3, in The GATT Uruguay Round: A Negotiating History (1986-1992), edited by **Terence P. Stewart**, Deventer/The Netherlands: Kluwer Law and Taxation Publishers (1993). Conversely, in GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, at

developing countries urged that the consequences of biotechnology protection should be assessed more carefully.[299]

The final text of the TRIPS Agreement suggests that within such a complex and controversial discussion a balance should prevail. The provision of the TRIPS Agreement which deals with biotechnology must be analysed as considering three matters in particular.

Note, firstly, that sub-paragraph (b) of Article 27 (3), TRIPS Agreement, authorises Members to exclude from patent protection "plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes". Carlos Correa[300] has expressed concerns in connection with two potential problems arising from the interpretation of this provision. He, firstly, examines the question of terminology when plants and animals are excluded from protection without any classification (varieties, races or species). This leads to a broad interpretation of the concept which includes plants and animals *per se*, as well as varieties, races and species of those which may be contradictorily excluded from patent protection by national laws. Secondly, Carlos Correa points out that the exclusion "essentially biological process" is limited by the reference to processes which are neither "non-biological" nor

---

p. 85, Nordic countries suggested basically the same as the EC proposal, adding that "[a]s regards biotechnological inventions, further limitations should be allowed under national law".

[298]GATT Doc. N. MTN.GNG/NG11/W/71, note 216, *supra*, p. 8, Art. 4 (1) (ii).

[299]See, *e.g.*, Peru's proposal in GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, p. 85. Canada, also, shared the views that with regard to the protection of biotechnology, a "... more technical study is required both domestically and internationally concerning the most appropriate form of protection and the conditions under which it should be accorded" (GATT Doc. N. MTN.GNG/NG11/W/47 (25 October 1989) Standards for Trade-Related Intellectual Property Rights, Submission from Canada, p. 7, point (iv)). Canada has thus proposed that Members should be allowed to deem not patentable "multicellular life forms or processes for producing new multicellular life forms" (*Ibid.*, at Annex, p. 11).

[300]Note 124, *supra*, at p. 328.

"microbiological". There are no complex doubts about "microbiological processes" as a matter capable of patent protection, in so far as the intention of the letter of Article 27 (3) (b), TRIPS Agreement, is to extend biotechnological protection to both traditional biotechnology and modern biotechnology. However, in connection with the introduction of the reference to processes with are "non-biological", it is not clear what the TRIPS Agreement wanted to define. As well put by Carlos Correa "[h]ow can a plant or an animal be produced by a process which is not totally or in part biological? The source and grounds of this text are untraceable"[301].

Secondly, the second sentence of Article 27 (3) (b) says that Members shall protect plant varieties. Nevertheless, Members may protect such a variety "... either by patents or by an effective *sui generis* system or by any combination thereof". Further analysis of such a provision, its consequences and its origins will be given below, in Section 3.

The last sentence of Article 27 (3) (b), TRIPS Agreement, may be regarded as the most important one, in so far as it states that the provisions of sub-paragraph (b) "... shall be reviewed four years after the date of entry into force of the WTO Agreement". It is clear that the negotiators of the TRIPS Agreement were not fully satisfied with the system they had themselves established for protecting biotechnology. Also, in the light of the negotiations of the Uruguay Round, one might say that neither developed nor developing countries agreed totally with what has been included in the final text. Coincidentally, such a four-year term for the revision of the TRIPS provision is exactly the same period as was given to developing countries to comply with the provisions of the Agreement. The discussion about biotechnology

protection is not settled on a world-wide basis. Further revision of this provision is expected to consider more carefully the ethical and moral issues which have not yet been completely clarified.

2.2. The legislation in Brazil

The CPI does not contain any exclusion regarding patent protection for animals, plants, micro-organisms or micro-biological processes. This is because it was only two years after the approval of the CPI that the first gene of a bacterium was cloned[302]. As a consequence of the silence of the law, 146 applications were filed in the INPI, between 1980 to 1990, for patents in the field of biotechnology, namely genetic engineering and mutations, while the two major areas in which patents have been sought are health and agriculture[303]. Almost half of those applications have been filed by US companies[304].[305]

Law 9279/96 establishes that the whole or part of natural living entities and biological material found in nature, or even that which has been isolated from nature, including the genoma and germoplasm from any living entity and natural biological processes, shall be excluded from patent protection[306]. It seems that the national legislature has decided to include a general rule - *i.e.* exclude from patent protection

---

[301] *Ibid.*

[302] See, *e.g.*, **Richard Burnett-Hall**, Environmental Law, London: Sweet & Maxwell (1995), at p. 779, note 2, where he says that "[t]he now standard DNA splicing techniques used in genetic engineering were first developed by Stanley Cohen and Herbert Boyer in around 1973".

[303] Appendix IV, Box 1, *infra*.

[304] Appendix IV, Box 2, *infra*.

[305] In a public debate held at the Committee of Economic Matters of the Federal Senate, on 10 August 1995, the Minister of Science and Technology of Brazil, José Israel Vargas, affirmed that the INPI is currently analysing over 300 patent applications in the area of biotechnology and patents have already been granted in the area of tissue culture (**Glaci Zancan**, Patentes: Não para Vegetais e Animais, *Jornal da Ciência Hoje*, 25 August 1995, p. 7).

[306] Law 9279/96, Art. 10 (IX).

everything which may be found naturally as a biological resource in the country - in order to determine how the implementation of the principles established by the Convention on Biological Diversity would take place. The aspects relating biotechnology to biological diversity will be discussed in more detail in Chapter 7, *supra*.

Several other aspects of the patentability of biotechnology have been included in the legislative debate of the Law 9279/96. The issue has been controversial and there has been strong opposition from certain sectors of the Brazilian economy and society. The debate has firstly been on whether micro-organisms should be protected or not and, then, whether micro-organisms should be defined, and, if so, whether micro-organisms should be protected as a process or as a product or as both[307].

Micro-organisms have not been defined in Law 9279/96. One of the arguments is that no satisfactory definition is possible[308], and that national juridical systems, together with the administrative structure granting intellectual property rights, should build a jurisprudential interpretation of what is meant by micro-organisms. An attempt to detail the law, at the current stage of doubt in this area, could make the law obsolete in just a few years[309].

The version of Law 9279/96 which was discussed in the Federal Senate under the number PLC 115/93, determined that animals and plants should be excluded from

---

[307] **Lucas Furtado**, Patenteamento de Microorganismos, Brasília: Assessoria Legislativa da Câmara dos Deputados, *mimeo*, 1993, pp. 4-5.

[308] Argument opposed by **Lucas Furtado**, note 307, *supra*, at pp. 4-5. He suggests two definitions for the term micro-organisms for legal application.

[309] See, generally, **Sociedade Brasileira para o Progresso da Ciência**, Patentes em Discussão no Senado, *Jornal da Ciência Hoje*, 25 August 1995, p. 1, where the Brazilian Minister of Science and Technology defends the view that micro-organisms should not be defined by Law 9279/96 (at that time PLC 115/93), but through complementary measures, which would be more easily update in accordance with the development of science.

patent protection and that micro-organisms would not be protected when isolated from an industrial process.[310] Patent applications for inventions related to micro-organisms would, nevertheless, be capable of protection since utilisation would occur only for a specific process which engenders a specific product. The interpretation of such provisions could lead someone to understand that all animal and plant varieties would be excluded from patent protection and that just the biotechnology process as such, not the product, would be capable of protection.

The final version of Law 9279/96, however, changed substantially, the wording of Article 18 (III), which now reads as follows:

> Art. 18 - The following are not patentable:
> I - ...
> II - ...
> III - the whole or part of living organisms, excluding transgenic micro-organisms which fulfil the three requirements of patentability - novelty, inventive activity and industrial applicability - listed in Article 8 and which are not discoveries.

Article 18, Sole paragraph, in addition, defines transgenic micro-organisms as organisms which, under direct human intervention in its genetic structure, expresses a characteristic which is not reachable by the said species in natural conditions. This excludes the whole or part of plants and animals.

The legislative evolution of the aspects of biotechnological protection of the Law 9279/96 seems to be in accordance with the international interests, since any organisms which has been under human intervention, and which holds a characteristic that is different than that which appears in natural conditions, will be capable of patent protection. Obviously, as stated by Article 18 (III), Law 9279/96, such transgenic

organism has to fulfil the requirements of novelty, inventiveness and industrial applicability. What is not clear is the cross-reference to the requirements of Article 8 and to the emphasis of discovery in the wording of Article 18 (III), Law 9279/96. Under the patent system, all the basic conditions of patentability will apply to all inventions. Also, discoveries are already excluded from patent protection, by virtue of Article 10 (I), but Article 18 (III), Law 9279/96, emphasises that transgenic micro-organisms which meet the basic requirements of patentability listed in Article 8, Law 9279/96, are capable of protection. It appears that such a repetition of the requirements of the law are not imperative and that was included only as a matter of unnecessary emphasis.

2.3. The negotiations in the MERCOSUL

National laws of Argentina, Paraguay and Uruguay do not refer at all to the protectability of biotechnology. Argentina and Uruguay have particularly considered the matter of plant variety protection and have specific legislation regulating that field, but have nothing in the field of biotechnology in general.

Neither the WIPO nor the Brazilian Proposal have considered this subject. The lack of common provisions on this matter might not be the most relevant issue in this context. The absence of a MERCOSUL patent granting body, together with the lack of a common way of harmonising jurisprudential interpretation, will create problems for all States Parties. There is no formal sign that the issue will be further considered

---

[310]PLC 115/93, Art. 18, (III).

in the near future. It is possible then to assume that regional negotiators are waiting for further developments which will occur under the auspices of the WTO[311].

3. *PLANT VARIETIES*

Plants are living organisms belonging to the "vegetable kingdom"[312]. Plants have always been essential nutrients and sources for medical therapy products, since the beginning of civilisation. They have the capacity of growing, living and breeding. Human practice, in the agriculture field, has intervened in the natural process - even though by very rudimentary methods - and has improved plants' capacities for, *inter alia*, producing more and better quality products and showing resistance against plagues and other climate or natural conditions.

Plant breeders were first recognised as proprietors of rights derived from the improvement of their plant varieties with an Edict published in 1883 by the Papal States. While recognising that men deserve the right to be rewarded for their research applied to the discovery of "... new products and, to the invention, improvement or introduction of new types of culture or technical solutions ...", the Recital of the Edict enacted by the Papal States, concludes that:

> We have now to concern ourselves with guaranteeing also the ownership of those works that relate to the progress of agriculture and its techniques by a more reliable and more expeditious method than

[311]The revision of the provisions in this matter, as determined by Article 27 (3) (b), Last sentence, TRIPS Agreement.

[312]The natural world may be divided in three areas: "animal, plant/vegetable and mineral kingdoms" (**A.P. Cowie** (ed.), Oxford Advanced Learner's Dictionary, Oxford: Oxford University Press (1989), 4th ed.).

> that practised hitherto with respect to the grant of specific exclusive privileges.[313]

Although the Edict provided for industrial property mechanisms for the protection of the products related to agriculture, such as the enjoyment of exclusive temporary rights, grace periods for failure to work, and term of protection, these regulatory provisions were never put into effect.[314]

Later, the Diplomatic Conference on the Paris Convention, which concluded work in 1883, decided upon a Final Protocol, considered as an integral part of the Paris Convention, which says that "[t]he words 'industrial property' should be understood in the broadest sense; they relate not only to the products of industry in the strict sense but also to agricultural products (wines, grain, fruit, cattle, etc.) ..."[315].

Then, at the beginning of the century, strong pressures from the agricultural sector forced the US government to enact a law in 1930, in which a special type of patent (plant patents) would be granted by the US Patent Office for the asexual reproduction of new plant varieties, excluding 'tuber plants'[316]. After being amended twice, in 1952 and 1954, this Act was included as an specific chapter in the Title on patents in the US Code.[317]

Further developments on the issues of plant protection, either by patents or by a breeders' rights system, have been considered at different levels of international,

---

[313]As quoted by **André Heitz**, The History of Plant Variety Protection, in **UPOV**, The First Twenty-Five Years of the International Convention for the Protection of New Varieties of Plants, Geneva: UPOV (1987), pp. 53-96, at p. 60.
[314]*Ibid.*, pp. 60-61.
[315]*Ibid.*, p. 59.
[316]Essentially potato and Jerusalem artichoke.
[317]**André Heitz**, note 313, *supra*, pp. 63 and 64; and UPOV Doc. N. UPOV/INF/11 (10 December 1985) The Protection of Plant Varieties and the Debate on Biotechnological Inventions, presented for the information meeting of January 10, 1986, p. 12, note 13.

regional and national laws. Developments have taken place at all three levels, as will be seen below.

3.1. International legislation

In the late 1950s, international efforts were devoted to the establishment of an international arrangement regulating the protection of plant varieties. In its second session, in 1961, the Diplomatic Conference for an International Convention for the Protection of New Varieties of Plants, concluded work on the UPOV Convention, which was recently updated in 1991.

Questions, and probably attempted solutions, have also been established by the concluded TRIPS Agreement of the Uruguay Round. The interface between plant patents, breeders' rights and advanced biotechnology has not been clearly concluded yet. These, and other issues, will be analysed under the international discussion below.

3.1.1. The UPOV Convention

The needs of breeders have brought pressures to bear upon national governments and the international community for a more appropriate type of protection for newly bred varieties of plants. Although a small number of countries have been granting breeders' rights through the traditional system of patent protection, the latter did not seem to be a system which would consider, in more detail, the characteristics of a protectable plant variety, therefore not satisfying the needs of the agricultural community.[318] This is, in summary, the reason for the establishment of an international arrangement in the field of plant varieties.

The UPOV Convention establishes a Union for the Protection of New Varieties of Plants, with legal personality[319], and whose Members are Contracting Parties to the UPOV Convention[320]. The Union has its seat in Geneva, Switzerland[321], and has as its permanent organs, the Council and the Office of the Union[322].

The Council, which consists of the representatives of the Member of the Union[323], meets at least once a year, in ordinary session[324], and has the task of *inter alia* appointing the Secretary-General of the Office[325], studying appropriate measures to safeguard the application of the provisions of the UPOV Convention[326] and taking all necessary decisions to ensure the efficient functioning of the Union[327]. The Office of the Union carries out all duties and tasks entrusted to it by the Council[328], under the direction of a Secretary-General[329], who will be responsible for all the administrative, financial and budgetary measures necessary for the functioning of the Union[330]. The official languages of the Union are English, French, German and Spanish[331].

Under the UPOV Convention, Members shall protect breeders' rights[332], where a "breeder" is the person who bred, or discovered and developed, a variety, or his successor in title[333].

---

[318] *Ibid.*, UPOV Doc. N. UPOV/INF/11, pp. 13-14, para. 20
[319] UPOV Convention, Art. 24 (1).
[320] *Ibid.*, Art. 23.
[321] *Ibid.*, Art. 24 (3).
[322] *Ibid.*, Art. 25.
[323] *Ibid.*, Art. 26 (1).
[324] *Ibid.*, Art. 26 (3).
[325] *Ibid.*, Art. 26 (5) (iii).
[326] *Ibid.*, Art. 26 (5) (i).
[327] *Ibid.*, Art. 26 (5) (x).
[328] *Ibid.*, Art. 27 (1), First sentence.
[329] *Ibid.*, Art. 27 (1), Second sentence.
[330] *Ibid.*, Art. 27 (2) and (3).
[331] *Ibid.*, Art. 28 (1).
[332] *Ibid.*, Art. 2. Whether dual protection should be allowed has been a matter of some controversy. During the 1991 Diplomatic Conference for the revision of the UPOV Convention an amendment to the mandatory provision of Article 2 (which reads "Each Contracting Party shall grant and protect

Two initial points must be highlighted here. Firstly, it should be noted that the employer is entitled to be defined as the breeder if the person who has bred, discovered or developed a variety is under his employment and the law of the Contracting Party so provides. Also, it is important to note that discoveries of new plant varieties are protected under the UPOV system of laws. UPOV states that it appears necessary to have the protection of discoveries for new varieties of plants because "... a large number of valuable new varieties are obtained by the selection and reproduction of plants that owe their existence to a spontaneous mutation (that is one which has not been artificially obtained and is therefore not repeatable at will, at a given moment)"[334].

Protection under the UPOV system applies to all plant genera and species[335], and lasts for a minimum of twenty years, counted from the date of the grant of the breeder's rights[336]. National treatment[337] and right of priority[338] principles shall apply. The UPOV system requires Members to provide that a plant variety must fulfil the

---

breeders' rights") was filed. Denmark and Sweden have jointly proposed (1991 UPOV Conference Records: Proposal for the amendment of Article 2 - DC/91/33 (4 March 1991), p. 108 and Proposal for the Amendment DC/91/51 (5 March 1991)) that breeders' rights as granted in the UPOV system should be the only form of protection which would be allowed to Members of the UPOV Convention. From the records of the discussion of the 1991 UPOV Diplomatic Conference (1991 UPOV Conference Records, pp. 212-218, para. 248-272) it is possible to affirm that the actual text of Article 2 is not clear in its entirety. In my opinion, Members of the UPOV have to protect breeders' rights, under the conditions and limits established by the convention. They may, however, do so using either patents or a *sui generis* system of protection, or both. In the case of patents or another system, for protecting plant variety rights, national laws will have to be amended, however, to comply with the UPOV mandatory conditions: *i.e.* novelty, distinctness, uniformity and stability.

[333]*Ibid.*, Art. 1 (iv).

[334]UPOV Doc. N. UPOV/INF/11, note 317, *supra*, p. 16, para. 23.

[335]UPOV Convention, Art. 3.

[336]*Ibid.*, Art. 19 (2), First sentence. For trees and wines, breeders rights shall be granted for a period not shorter than twenty five years (*Ibid.*, Art. 19 (2), Second sentence).

[337]*Ibid.*, Art. 4.

[338]*Ibid.*, Art. 11.

conditions of novelty, distinctness, uniformity and stability, in order to be protectable[339].

The concept of novelty under the UPOV framework differs substantially from its definition in patent laws. With regards to the latter, an invention will be considered new if it is not part of the prior art, where prior art is understood as everything which has been made available to the public. In the light of the UPOV Convention, a plant variety will be considered as included in the prior art - and as such not protectable - if the right holder, or someone with his consent, has commercialised or disposed of the plant variety, for purposes of exploitation of the variety[340].

The condition of distinctness is considered fulfilled if the plant variety for which protection is sought is "clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application"[341]. Further, a plant variety will be deemed to be uniform if it is sufficiently uniform in its characteristics[342]. And, finally, a variety shall be considered stable if "... its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle or propagation, at the end of each such cycle"[343].

Pursuant to Article 14 (1) (a) of the UPOV Convention, the following acts related to the protected variety may not be carried out without the express authorisation of the breeder, who may give his authorisation subject to certain conditions and limitations[344]: (a) production or reproduction (multiplication); (b)

---

[339] *Ibid.*, Art. 5 (1). Members are not allowed to impose on applicants further and different conditions (*Ibid.*, Art. 5 (2)).
[340] *Ibid.*, Art. 6 (1).
[341] *Ibid.*, Art. 7.
[342] *Ibid.*, Art. 8.
[343] *Ibid.*, Art. 9.
[344] *Ibid.*, Art. 14 (1) (b).

conditioning for the purpose of propagation; (c) offering for sale, selling or other marketing; (d) exporting or importing; and (e) stocking for any of the purposes mentioned above. [345] These acts are not exhaustively imposed by the UPOV system. Parties may therefore provide in their national legislation for further activities which require the authorisation of the breeder[346]. These legal requirements, as related with the rights conferred to breeders, shall also apply to (a) varieties which are essentially derived from the protected variety, (b) varieties which are not clearly distinguishable from the protected variety, and (c) varieties whose production requires the repeated use of the protected variety[347]. It is also worth noting that breeders' rights may be subject to compulsory licences, but only on grounds of public interest and that such a non-voluntary licence must ensure that the breeder receives equitable remuneration for the use of his rights[348].

It is also important to mention that once the breeder, or someone else with his consent, has sold or marketed any material[349] of the protected variety or any material derived from the latter, his rights will be exhausted in that specific national market[350]. The exhaustion of rights principles shall not apply to the acts of selling or marketing the material of a protected variety when such acts involve further propagation of the

---

[345]Note that the above-listed acts in respect of harvested material, including entire plants and parts of plants, which have been obtained through the unauthorised use of propagating material of the protected variety (*Ibid.*, Art. 14 (2)); and acts in respect of products made directly from harvested material through the unauthorised use of the said harvested material (*Ibid.*, Art. 14 (3)); shall require the authorisation of the breeder, unless he has had a reasonable opportunity to exercise his right in relation with the said propagating material.

[346]*Ibid.*, Art. 14 (4).

[347]*Ibid.*, Art. 14 (5). Conversely, the rights granted to breeders will not apply to (a) acts done privately and for non-commercial purposes, (b) acts done for experimental purpose, and (c) acts done for the purpose of breeding other varieties (*Ibid.*, Art. 15 (1)).

[348]*Ibid.*, Art. 17.

[349]For the purposes of the application of this principle "material" in relation to a variety means propagating material of any kind, harvested material (including entire plants and parts of plants) and any product derived from the harvested material (*Ibid.*, Art. 16 (2)).

variety in question or include the exportation of the material of the variety into a country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported material is for final consumption[351].

3.1.2. The TRIPS Agreement

The issues about the patentability of new varieties of plants were formally considered as a specific subject in the TRIPS negotiations. Discussions in this field were always included in the negotiations about the provisions on the protection of biotechnological products and processes. The provision of the TRIPS Agreement regulating this matter is necessarily based on the proposal of the EC which was based on the wording of the EPC[352].

The EC suggested, in the first place, that plant varieties and essentially biological processes for the production of plants should be excluded from patentability[353]. Although the EC considered initially that plant varieties should not be patentable at all, it suggested later that Members would be allowed to exclude new varieties of plants from patentability[354], but under the obligation to protect new varieties of plants by patents or by an effective *sui generis* system[355]. It means that, bound by the commitments reached in the Uruguay Round, Members may choose the appropriate system for protecting plant varieties.

---

[350]*Ibid.*, Art. 16 (1).
[351]*Ibid.*, Art. 16 (1) (i) and (ii).
[352]See Article 53 (b) of the EPC.
[353]GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2, note 122, *supra*, p. 85. See, also, in the same page of this document, similar proposals from the Nordic countries and Peru.
[354]GATT Doc. N. MTN.GNG/NG11/W/68, note 297, *supra*, p. 10, Art. 23 (2).
[355]*Ibid.*, p. 10, Art. 23 (3).

The agreed text of the TRIPS Agreement, namely Article 27 (3) (b), includes the EC suggestion. It has gone further and considered that not only could patents or an effective plant breeders' rights system be used, but also any combination of both legal systems may be used by Members of the WTO Agreement to protect new plant varieties.

Though it is not expressly mentioned in the actual text, the TRIPS Agreement has taken into consideration further developments of the UPOV Convention, and the best example of the *sui generis* system, as proposed by Article 27 (3) (b), is the one of the UPOV. The statement of the representative of GATT, during the 1991 Diplomatic Conference for the revision of the UPOV Convention, emphasised that the Uruguay Round negotiations had not reached an agreement in the discussion of the patentability of plant varieties. Negotiators have thus opted for a more flexible method, and Members would be free to decide whether to use patents, a *sui generis* system - "such as the UPOV system" - or any combination of both[356].

It is noteworthy, lastly, that the last sentence of sub-paragraph (b) of Article 27 (3) calls for a review of the provisions on biotechnology and, also, plant varieties, in expectation of further international legal developments in the field of the protectability of plant varieties.

3.2. The legislation in Brazil

The protection of the rights over new plant varieties was firstly recognised in Brazil by Decree Law N. 2.679, of 7 October 1940, which aimed to regulate the registration and requirements of industrial property attorneys before the National Department of

Industrial Property. In Article 1, Sole paragraph, of Decree-Law No. 2.679/40, new plant varieties are considered as an industrial property right, capable of protection in this field of law. It affirmed that "[t]he protection of industrial property refers to all industry and commerce, applying to the inventions which deserve the privilege, utility models, industrial design or model, new varieties of plants, trade marks, ...".

No industrial property application for plant varieties has been filed in the Brazilian industrial property office. The CPI, for instance, does not refer at all to the protection of new varieties of plants.

PL 824/91, in its original version as submitted by the Brazilian President to the National Parliament, considered that all non-modified biological material found in nature could not be an invention[357]. Further, the first version of the Bill stated that patents would not be granted to plant varieties[358] and that a specific law would regulate such a subject[359].

The final version of PL 824/91, *i.e.* Law 9279/96, does not suggest explicitly that plant varieties should be protected by a *sui generis* system. It merely excludes from patentability all living matter[360]. It seems that the national legislature did not deem it necessary to refer explicitly to the subject. The expectation is that a *sui generis* system, in accordance with the UPOV Convention, will be established in the near future[361].

---

[356]In 1991 UPOV Conference Records, at p. 180, paras. 74.1 and 74.2.
[357]PL 824/91, Art. 10 (IX). The discussion in the Federal Senate, where the legislative Bill was numbered as PLC 115/93, under the same Article number, improved the writing of such provision but maintained the general principle. The final version, Law 9279/96, contains the same wording of that of PLC 115/93.
[358]PL 824/91, Art. 18 (III).
[359]*Ibid.*, Art. 18 (2).
[360]Law 9279/96, Art. 18 (III).
[361]**Glaci Zancan**, note 305, *supra*, contains information on a declaration by the Brazilian Minister of Science and Technology who affirms that the Brazilian government is negotiating towards the

Senator Odacir Soares proposed a Bill, numbered as PLS N. 199, of 22 June 1995 (PLS 199/95), establishing rights over the development or discovery of new varieties of plants. Institutionally, it is established under the auspices of the Ministry of Agriculture, the National Service for the Registration and Protection of Plant Varieties (SNRPC). The SNRPC, which will have its administrative organisation determined by specific legislation[362], will be the authority in charge of the registration and protection of new plant varieties[363].

PLS 199/95 will make protectable a new variety of plant, as described in specialised publications available to the public, which is clearly distinguishable[364] from other known varieties, with specific denomination, and that is homogeneous[365] and stable[366].[367] The subject-matter of the protection is the reproduction or multiplication material of the whole plant[368].

The right entitles its holder to reproduce a new variety commercially in the Brazilian territory. The acts of selling, offering to sell, reproducing, importing, exporting, packing, storing or assigning the new variety are allowed to third parties only with the holder's consent.[369]

---

accession of Brazil to the UPOV Convention and that Brazil was therefore considering further measures in this field.

[362]PLS 199/95, Art. 1.

[363]*Ibid.*, Art. 43. The tasks and objectives of the SNRPC are provided in more detail in Articles 44 to 57, PLS 199/95.

[364]A variety shall be considered distinct when it is clearly different from any other variety which, at the date of the registration is known (PLS 199/95, Art. 4 (IV)).

[365]A variety is homogeneous when it is utilised in the plantation, in a commercial scale, and presents minimum variability in relation with the morphological, physiological or biochemical characteristics utilised in the description of the variety (PLS 199/95, Art. 4 (V)).

[366]A variety is considered stable when it is reproduced in commercial scale and it maintains its homogeneity through successive generations (PLS 199/95, Art. 4 (VI)).

[367]PLS 199/95, Arts. 3 and 6. If the variety does not hold any more the conditions of homogeneity or stability, the rights over that variety will not longer exist (*Ibid.*, Art. 36 (III)).

[368] *Ibid.*, Art. 7.

[369] *Ibid.*, Art. 8. This rule will not apply in three cases: (a) when someone plants or store the seeds for personal use (*Ibid.*, Art. 9 (I)); (b) when someone uses or sells, as foodstuff or raw material, the

Any person or legal entity, and their successors, may apply for protection[370]. When the applicant is a legal entity, the name of all the persons responsible for developing the new variety[371] will be provided[372] [373]

PLS 199/95 suggests that the term of protection shall be fifteen years, counted from the date of the grant of the breeders' rights. Fruit and ornamental plants shall be protected for a period of twenty five years.[374]

With regard to the granting of compulsory licences, PLS 199/95 says that a variety may be declared as of "restricted public use" on grounds of public interest or on grounds of abuse of dominant position, for a renewable period of two years[375]. In addition, Article 29 (1) defines "restricted public use" as the authorisation granted to third parties to exploit the variety, during the term fixed by the administrative authority, against the respective payment of royalties to the right holder.[376] The authorisation as proposed by this Bill, for the use of a variety by third parties, on grounds of abuse of dominant position, is against the mandatory rule of Article 17 (1)

---

product obtained from the cultivation of the variety (*Ibid.*, Art. 9 (II)); or (c) when the variety is utilised as source for genetic improvement or in scientific research (*Ibid.*, Art. 9 (III)).

[370] *Ibid.*, Art 5, *caput* and (1). Application for varieties which have been obtained by the efforts of two or more persons may be filed jointly or separately (*Ibid.*, Art. 5 (2)).

[371] The person who has bred, discovered or developed a new variety, in the light of the PLS 199/95, is called a "developer" (PLS 199/95, Art. 4 (I)). Although differently formulated from the definition provided by the UPOV Convention, the "developer" is actually the "breeder". He is the natural person responsible for the development of the new variety and for the establishment of the morphological, physiological or biochemical characteristics of the variety which may differentiate that variety from the others.

[372] *Ibid.*, Art. 5 (3). See, also, Articles 31 to 35, for the provisions on the development of a variety which occurred under the existence of an employment agreement.

[373] Foreign natural or legal persons are also entitled to protect their breeders' rights, under the application of the national treatment principle (*Ibid.*, Art. 10), if the country where the variety was developed recognises the rights over the varieties obtained in Brazil, similarly to those obtained in the foreign country (*Ibid.*, Art. 10, Sole paragraph).

[374] PLS 199/95, Art. 12. Note that national legislator will have to consider that, if the interest of the Brazilian government is to adhere to the 1991 UPOV Convention, such a term of protection does not fulfil the requirements of the UPOV, where the minimum term of protection is of twenty years (*Cf.* Art. 19 (2), UPOV Convention).

[375] *Ibid.*, Art. 29, *caput*.

of the UPOV Convention which limits the granting of a compulsory licence only to situations of public interest. This is another issue which is not in accordance with current moves towards Brazilian accession to the UPOV Convention. The current version of PLS 199/95 also fails to address the issues on the right of priority and exhaustion of rights.

3.3. The negotiations in the MERCOSUL

Only the national laws of Argentina and Uruguay provide for the protection of new plant varieties through a "breeders' rights" system. Both have also adhered to the UPOV Convention[377].

Neither of the legal instruments which have been proposed in the MERCOSUL negotiations refer to protectability of plant varieties. There is also no indication that the matter will be discussed in detail in the MERCOSUL, at least at this stage. The fact is that there is a regional trend among the States Parties of the MERCOSUL, to adhere to the UPOV system and therefore harmonise the protection of new varieties of plants.

CONCLUSION

The first thing to be said, as a conclusive remark arising from the present analysis, is that to undertake legislative actions towards the harmonisation of substantive patent law is a very complex activity and that current negotiations within the MERCOSUL

---

[376] An user who identifies the conditions established by Article 29 may also request to the Ministry of Agriculture the grant of a "restricted public use" on grounds of public interest (*Ibid.*, Art. 29 (2)).
[377] Argentina on 25 December 1994 and Uruguay on 13 November 1994 (WIPO Doc. N. 423 (E), note 293, *supra*, p. 25). The UPOV Convention has, as at 1 January 1996, thirty Members (*Ibid.*).

are not addressing this matter in detail. When one looks at the draft texts which have emerged from the negotiations in the MERCOSUL, these reveal a lack of detail in the provisions agreed so far. For example, it is possible to note that the WIPO Proposal is a very detailed text, but fails to address complex and controversial issues. It must be said that the WIPO Proposal does not form the basis for intellectual property discussion within the MERCOSUL. The "detailed" suggestion of WIPO should be understood rather as a list of provisions which could be included in the laws of the States Parties of the MERCOSUL or in a common agreement on industrial property. On the other hand, the Brazilian Proposal, which seems to represent more closely an outcome of the negotiating process towards a common set of norms for the MERCOSUL, is superficial and vague. The Brazilian Proposal fails to address not only the most controversial issues, but also matters related to very basic conditions for patentability. The Brazilian Proposal, unfortunately, seems to form the basis for industrial property discussion in the MERCOSUL.

As described above in Chapter 1, Section 2, Sub-section 2.3, Paragraph 2.3.1, the MERCOSUL has just recently defined a more precise institutional framework for its functioning. It lacks a judicial body, which would harmonise juridical interpretation and settle conflicts between national and community laws. This is particularly the case when looking at the issues on IPRs. There is a need for a more efficient legislative process, made effective and applicable by an administrative and a juridical structure.

It is true that the European Union, which is at a higher stage of integration, has not yet agreed upon a common and unified mechanism for patent protection within the Community, as has been generally described in Chapter 4, *supra*. Also, the MERCOSUL has different characteristics, features and established goals, if compared

with the EU. Within the context of an integrated market, and considering the differences among the national provisions which will be governing patent protection in the territory of the MERCOSUL, more careful consideration must be given to the application of general intellectual property principles. The lack of defined provisions and the absence of a harmonised system to interpret the legal framework of the MERCOSUL, may create problems in the near future. It is necessary to agree upon a more institutional approach. For the protection of IPRs, perhaps the setting up of a common administrative body, such as a patent office, which would analyse, judge and grant industrial property privileges, at an administrative level, could contribute to the necessary process of institutional and commercial integration.

All these institutional mechanisms, however, are only worth existing if a minimum set of common rules exist. The MERCOSUL has failed, so far, to discuss in depth several aspects of patentable subject matter. There is a need for more detailed provisions determining the conditions of patentability, exclusions and exceptions, term of protection, and rights conferred by a patent. In addition, there should be a detailed legal understanding about the application of each of those provisions which will be used throughout the territory of the MERCOSUL. Hence the negotiations should go beyond the simple process of listing industrial property principles. When one considers, for instance, the definition of the basic conditions of patentability - *i.e.* novelty, inventiveness and industrial applicability - it is necessary to bear in mind that if there is no definition on how national patent offices should address these issues, a diverse application of these conditions will definitely occur. Moreover, the conditions for the granting of compulsory licences should be limited, to fit into the necessary boundaries of an integrating project. These are introductory issues which deserve

careful consideration in the context of a common agreement to harmonise patent protection in the MERCOSUL. It is also necessary to consider the establishment of limits for the setting up of the conditions and obligations for the use of the patent *vis-a-vis* the requirement of local production of the protected product.

Particularly in relation with the latter issue, States Parties of the MERCOSUL should bear in mind that the TRIPS Agreement establishes that Members of the WTO Agreement must accept importation as a condition of the use of a patent. The example of the recently approved Brazilian industrial property law could provide some guidance in this regard, in so far as it determines that importation will be accepted as the use of a patent only if the patentee proves that the conditions for local production are economically impossible. This is, for example, the situation of products which do not have a market which justifies its local production. Otherwise, local production should be required.

Some could argue that the TRIPS Agreement does not allow such interpretation from the wording of Article 27 (1) which says that "... patents shall be available and patent rights enjoyable without discrimination as to the place of the invention, the field of technology and whether products are imported or locally produced".[378]

The foregoing reference to Article 27 (1) of the TRIPS Agreement have to be read in conjunction with Articles 7 and 8 of the same Agreement. Article 7 of the TRIPS Agreement determines that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and

---

[378]See, for further discussion on the application of Article 27, TRIPS Agreement, **Peter Kolker**, Should Importation Be Considered as working? A Study of Article 27 of the GATT/TRIPS Agreement, London: The Intellectual Property Institute (1996).

dissemination of technology. It is quite clear that such promotion, transfer and dissemination of technology would only take place effectively if production of the patented product occurs in the place where such product will be commercialised. Article 8 (1), TRIPS Agreement, goes further and determines that Members of the WTO Agreement, when implementing the provisions of the TRIPS Agreement, may adopt measures to promote the "...public interest in sectors of vital importance to their socio-economic and technological development ...". The adoption of national measures must be done in accordance with the TRIPS Agreement, but, by virtue of Article 8 (2), TRIPS Agreement, a broader interpretation of the wording of the TRIPS Agreement may be necessary to prevent practices "... which unreasonably restrain trade or adversely affect the international transfer of technology". Local production of a patented product, as a means of promoting the necessary transfer of technology, is a possible mechanism that is not contrary to the letter of the TRIPS Agreement. On the one hand, the TRIPS Agreement's goal is to promote enforcement and harmonisation of intellectual property laws, while supporting the dissemination and transfer of technology. On the other hand, the TRIPS Agreement recognises the technological gap between developed and developing economies, by granting the latter, in Article 65, an extra period of time to implement the provisions of the TRIPS Agreement.

Furthermore, when one looks at the issues on patentable subject-matter, particularly those related with the protectability of pharmaceuticals, biotechnology and plant varieties, even more detailed analysis should be included in a common text aiming at the harmonisation (or unification) of national laws in the MERCOSUL. The setting up of common provisions for the protection of the above mentioned issues,

however, have to be drawn up within a much broader context. Science and technology, as well as industrial and environmental policies have to be part of the legislative considerations of these matters. Further conclusions in this regard will be provided in Chapter 7, which draws up a line between patent protection and the exploitation of natural resources, and in the final conclusion, below.

When one considers particularly the conceptual aspects of patentability of pharmaceuticals and biotechnology, several considerations must be made. For pharmaceuticals, a common arrangement on the harmonisation of national patent laws in the MERCOSUL must consider the issues on pipeline protection (as a means of implementing the TRIPS Agreement), and procedural matters, such as the second and further uses of known substances or products. With regards to the discussion whether pharmaceutical products and processes should be protected or not, this seems to be a debate which belongs to the past. States Parties of the MERCOSUL are obliged by the TRIPS Agreement to protect pharmaceutical products and processes. If States Parties have to protect them, a common and unified understanding of the issue has to be included in the common text on patent rights for the MERCOSUL.

In the field of biotechnology, possible provisions of a common agreement in the MERCOSUL will have to consider, firstly, the non-finalised agreement in this matter in the international forum. The TRIPS Agreement, as has been described in Part 2, Section 2, Sub-section 2.1, Paragraph 2.1.2, *supra*, provides a doubtful and vague definition of biotechnological protection. The wording of the TRIPS Agreement is not clear and leaves much discretion to national laws to interpret its letter. Further, by calling for a revision of Article 27 (3) (b) of the TRIPS Agreement, the negotiators accepted that the discussion about the protection of biotechnology has

not yet been concluded. Therefore, a common agreement on patents for the MERCOSUL has to determine provisionally the ethical, social, economic and technological circumstances of the region, though accepting that some degree of protection for biotechnological products is necessary. The MERCOSUL should provide technology owners and users with some expectation of legal certainty. Common provisions on the protection of biotechnology should attempt to define the concepts on a provisional basis, making sure that a definite set of rules for biotechnology would become available once the international community, particularly under the TRIPS Agreement, agrees upon a clearer provision in this field.

With regards to the protection of plant varieties, it is more likely that negotiations would move towards a breeders' rights system, under the UPOV auspices. As has been mentioned in Part 2, Section 3, Sub-section 3.3, above, Argentina and Paraguay are already Contracting Parties to the UPOV Convention and Brazil is negotiating accession to the UPOV Convention and discussing, in Parliament, a breeders' rights system of protection. The discussion on the harmonisation of laws and regulations for the protection of plant varieties has, thus, to be considered separately from the discussion on patent harmonisation.

Another aspect that I should like to mention is related to the legislative mechanism which will be utilised for the harmonisation of substantive patent laws in the context of the MERCOSUL. The diverse application of the several aspects related to the protection of pharmaceuticals, biotechnology and plant varieties will probably lead the negotiating process in the MERCOSUL to discuss these issues under separate legal frameworks. It is difficult to foresee a common agreement covering in detail all these complex and distinct matters. In my opinion, there are more

appropriate legislative measures to harmonise all these issues which may be taken by the organs of the MERCOSUL and which are directly binding upon the States Parties. This appears to be more feasible than the mechanism of inter-State Convention. Past negotiations on common rules for patent protection through the mechanism of inter-State Convention in the MERCOSUL could be used to back up future negotiations under a new approach which considers other legislative methods that will discuss each issue in a separate way.

The present Chapter attempted to describe the international and national trends on substantive patent law, informing the reader about the current stage of the negotiations in the MERCOSUL. The following Chapter will take a similar path and describe the international and national trends on integration-related aspects of IPRs (*i.e.* free movement of goods and competition law principles), informing the reader about the current stage of negotiations in the MERCOSUL. The descriptive analysis that follows intends to be complementary to that of Chapter 3, below.

CHAPTER 6
SUBSTANTIVE PATENT LAW: COMMERCIAL ISSUES

INTRODUCTION

Envisaging a commercially integrated market, as first put into practice by the European Community, there are, *inter alia*, two important principles to be considered for the success of the process itself, which are of particular concern to the present research. They are the principle of free movement of goods and the mutual application of competition rules throughout the territories of the participating countries.[1] These common constitutional provisions of regional arrangements are of particular interest when analysed under the understanding that patent rights are granted nationally - or if granted in a regional basis, that these rights will certainly be analysed by national courts as national patents[2] - and that the resulting goods will be marketed in that territory, without being subject to any type of quantitative restrictions or any measures having equivalent effect[3].

The first principle is that goods shall circulate freely throughout the territory of the Member States, without being affected by tariff or non-tariff barriers[4]. This is a principle which, together with the so-called "four freedoms"[5], specifies the essential features and goals of political arrangements towards a free trade zone, a customs

---

[1]See, generally, the main structure of part 4 of the work done by **David A. O. Edward & Robert C. Lane**, European Community Law: An Introduction, Edinburgh: Butterworths & Law Society of Scotland (1995), 2nd ed., and, particularly, pp. 76 to 86 and 102 to 121.
[2]See, generally, Chapter 4, *supra*.
[3]EC Treaty, Art. 30. **Peter Oliver**, Free Movement of Goods in the EEC under Articles 30 to 36 of the Rome Treaty, London: European Law Centre Limited (1982), at p. 1, says that the application of the principle, as established by Article 30, "... covers a multitude of other trade restrictions ..." covering "... such questions as intellectual property, price controls and indications of origin".
[4]The "free movement of goods" principle as established by regional agreements. See, *e.g.*, Articles 30-36 of the EC Treaty and Article 1 of the Treaty of Asuncion.
[5]Free circulation of goods, persons, services and capital.

union or a Common Market. The temporary monopoly conferred by the State upon an intellectual property holder may, in some cases, infringe the principle of free movement of goods. This problem has been dealt with, particularly in European case law[6], by widening the territorial application of the principle of exhaustion of patent rights.

Additionally, it is indispensable for the establishment and functioning of an integrated economic and commercial area that competitive practices in the territory of the participating countries do not affect the process of liberalisation of trade in that particular integrated area[7]. Again, the exercise of the right of a patent may, in some circumstances, affect trade between Member States, which shall be deemed unlawful.

The European Court of Justice and the Commission of the European Communities have played a very significant part in the process of commercial integration in Europe. Both the free movement of goods and competition law principles, as studied in Chapter 3, have been frequently used as a very important guide and reference for future integrating projects.

In this Chapter, the concerns about the application of the free movement of goods and anti-competitive rules will be analysed on the international, national and regional levels. Again, following similar structure to Chapter 5, relevant agreements, laws and regulations will be considered as follows.

When analysing the questions related to the application of the principle of the free movement of goods, and the consequent exhaustion of patent rights in a specific territory, Section 1 studies the provisions of the TRIPS Agreement for an

---

[6]More detailed discussion on European case law in this field is provided by Chapter 3, Section 1, *supra*.

international view. Then, it discusses the issues under Brazilian national legislation, paying particular attention to the CPI and the relevant aspects of parliamentary negotiations of Law 9279/96. Lastly, the issues are analysed in the context of the negotiations carried out in the MERCOSUL.

When analysing the issues on competition law, Section 2 considers, at the international level, the Paris Convention and the rules established by the TRIPS Agreement. At the national level national legislation on competition law, the CPI and the parliamentary negotiations of the Law 9279/96 will be studied. At supranational level, Section 2 analyses the application of Article 4 of the Treaty of Asuncion and current stage of negotiations towards common rules on competition law.

1. *Free Movement of Goods*

The free movement of goods principle has been commonly applied by national laws when connected with the use of intellectual property rights in national territories. When rights are granted by the State to a patent holder, at the same time the use and the exploitation of these rights are limited to national boundaries. That is the essence of an intellectual property right. The international community has attempted to harmonise, multilaterally, the application of intellectual property principles, while avoiding the discussion on the international exhaustion of IPRs.

This is of particular interest when, in the context of an integrated market, it is said that participating countries must not impose restrictions on the circulation of products. In this particular case, the application of patent rights are considered with great care. The holder of a patent has a temporary monopoly which allows him to

---

[7] See, *e.g.*, Articles 3 (g) and 85 to 94 of the EC Treaty and Article 4 of the Treaty of Asuncion.

exploit the patented invention and to be rewarded for the financial investments and the efforts which have led to the invention. The exercise of his right has nevertheless to be limited. The analysis in Chapter 3 concluded that, in the European Community, once a patent holder, or someone with his consent, markets the patented product for the first time in the territory of one of the Member States of the Community, his rights over the distribution of that product are exhausted and he is not allowed to impose any barriers to the further circulation of the patented product in the Community.

1.1. International legislation: the TRIPS Agreement

The debate about the exhaustion of intellectual property rights has been a major line of distinction between the interests of developed and developing countries. The former understands that the exhaustion of rights doctrine should remain as traditionally applied, within national jurisdictions. Developing countries, on the other hand, argue that the principle of exhaustion of rights should apply on an international basis.

The differences of view in this regards are essentially based on the further commercialisation of the patented product. While developed countries, which are the owners of technology, want to have monopoly rights over patented products in a national basis, thus impeding further circulation of the protected product in an international basis without the owners' consent, developing countries want to have the possibility of acquiring protected products wherever in the world they have been marketed at lower prices. Under the national exhaustion system, intellectual property owners would be allowed to license their protected products in every national territory and the product in question could not be exported to other countries unless

the owner authorises someone else to do so or does so himself. On the other hand, under the international system of exhaustion of IPRs, protected products would be allowed to circulate freely throughout the world, after being introduced into the market by the right holder or someone with his consent, eventually enhancing competition and keeping prices down.

This discussion has been of particular concern during the negotiations of the TRIPS Agreement, though neither developed nor developing nations have explicitly referred to the issues of international exhaustion of IPRs.[8] In general both groups of countries insisted that IPRs should not be used as barriers to international trade, which was the most important goal to be achieved by the TRIPS Agreement. Thus, it is important to remark that, in essence,

> ... international exhaustion corresponds more to the spirit of GATT since it does not rely upon the exceptions provided for in Articles XX (d) and XXIV on customs unions and free trade areas. Licensing ideally implies, from a GATT perspective, that new competition is created which is beneficial from a point of view of efficiency.[9]

It is necessary to remark that, from the reading of the negotiating documents of the TRIPS Agreement "[n]o party was willing to make any commitment in this complex field, which is often left to national courts"[10] and national laws.

---

[8]Note, however, that during the negotiations on the PLT, a group of developed countries has taken a position that "[t]he right to control importation was ... a necessary corollary to the right to make the patented product" and that "[t]he right to prevent the making of a patented product was only controllable territorially, and a loophole in the protection would occur if a third party could import an infringing product manufactured in a country other than the country where the patent had been granted" (PLT I Conf. Rec., p. 511, para. 116.7). In addition, the representative to the Soviet Union has expressed its position in favour of Alternative B, of Article 19, PLT, which says that the exhaustion of rights principle may be accepted either nationally or in a regional basis (*Ibid.*, p. 515, para. 120.3).

[9]**Thomas Cottier**, Intellectual Property in International Trade Law and Policy: the GATT Connection, *Aussenwirtschaft*, 47 Jahrgang (1992), 79-105, at 97.

[10]**Thomas Cottier**, The Prospects for Intellectual Property in GATT, [1991] 28 *CML Rev.* 383-414, p. 399.

The final agreement on TRIPS has thus established that nothing in the TRIPS Agreement "... shall be used to address the issue of the exhaustion of intellectual property rights" for the purposes of dispute settlement procedures[11]. Although it is possible to affirm that this provision has "caused a considerable amount of disquiet in some circles" - presumably the industries of developed nations which feared that it would impose a system of international exhaustion of IPRs[12] - most authors, when analysing this issue, have understood that this is a "neutral" type of provision which leaves to national legislation and courts the discretion to adopt whichever system is deemed better[13].

It is also noteworthy that the GATT provisions, in particular Article XX (d), allow Parties to adopt and enforce national legislative or regulatory measures in relation to IPRs if the following conditions are met: (a) if these laws and regulations are not contrary to the GATT law; (b) if these laws and regulations are necessary to secure compliance with GATT law; and (c) if such measures are not applied in a manner which would constitute either a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.

In fact, GATT enables parties to take legislative measures which, otherwise, would be contrary to its principles. A broader interpretation of Article XX (d) could nevertheless lead one to think about the obligation imposed upon Contracting Parties to apply the principle of international exhaustion of rights, in so far as national

---

[11]TRIPS Agreement, Art. 6.

[12]**Jörg Reinboth & Anthony Howard**, The State of Play in the Negotiations on Trips (GATT/Uruguay Round), [1991] 5 *EIPR* 157-164, p. 159.

exhaustion may be considered restrictive of international trade, constituting a barrier to the free flow of goods and hence contrary to GATT principles. This interpretation is not clear though and, taking into account the foregoing discussion on Article 6 of the TRIPS Agreement, it is possible to argue that the application of Article XX (d) to international exhaustion of rights is no longer effective because the TRIPS Agreement has explicitly allowed its Members to adopt either national or international jurisdiction on the application of the exhaustion of rights doctrine.

1.2. The legislation in Brazil

The CPI has not dealt with the issues of international exhaustion of patent rights. Juridical and administrative understanding has however applied the international exhaustion doctrine in Brazil as a general rule.

The negotiations towards Law 9279/96 in the Brazilian Parliament considered this matter in more detail. In the first version submitted to Parliament, the principle of international exhaustion was present. The rights of a patentee would be considered exhausted once the patented product had been put into the national or international market by the patent holder, or by someone with his express consent. As highlighted by Mensagem Presidencial N. 192/91, the option for the inclusion of the international exhaustion principle in a new legal framework considered, particularly, the Brazilian national policy of free market which took into account GATT existing rules[14].

---

[13]See, generally, **Jörg Reinbothe & Anthony Howard**, note 12, *supra*, **Thomas Cottier**, note 10, *supra*, and **Clive Bradley**, The Role of GATT in Intellectual Property, [1991] 3 *Copyright bulletin* 11-15, p. 14.

[14]See, above, in Sub-section 1.1, a description of some concerns that have been expressed in relation to the interpretation of Article 6 of the TRIPS Agreement. It seems to be clear, as it has been pointed out in Sub-section 1.1, *supra*, that the goal of Article 6 of the TRIPS Agreement appears to be that

It was clear from the beginning of the negotiations of Law 9279/96 that Members of Parliament in Brazil were not very familiar with the consequences of the application of such principles. Questions have then arisen from the understanding of the principle as related to the patentee's right to impede someone from exporting or importing the patented product without the consent of the patent holder. Actually, what seems to have been the doubtful concern of the Brazilian Parliament was the limitation applied to the application of the rights to impede someone to export or import the patented product. After some clarification it appeared that the patentee will have the exclusive right to market the patented product, or to authorise someone to do so, anywhere in the world. If someone else does so, on a national or international basis, without the patentee's express authorisation, this act will be deemed unlawful and thus subject to criminal and/or civil sanctions and penalties.[15]

Law 9279/96 deals with the subject as follows. Where the rights of the patentee are established[16], Law 9279/96 says, in Article 43 (IV), that the rights conferred to the patentee will not apply to products which have been manufactured in accordance with a product or process patent which has been put into the internal or external market directly by the patent holder or with his consent.

Opting for the international exhaustion doctrine, Brazilian legislation seems to be moving towards the protection of its own industries and technologies. Note that, as an importer of technology, Brazilian industries would be allowed to import products

---

national Parliaments and national courts are free to adopt either the national or the international system of exhaustion of IPRs.

[15]See, generally, discussion during the Seventh, Tenth and Twelfth Meeting of the Special Committee of the Chamber of Deputies, where some discussion took place in relation to the inclusion of the international exhaustion of IPRs doctrine into Brazilian legal framework. It is noteworthy that no controversy has taken place, but only some doubts concerning the application of such principle.

[16]As described in Chapter 5, Part I, Section 3, *supra*.

which are manufactured in other countries, with the patentee's consent or by himself, where such product is marketed with cheaper prices. This seems to be of particular importance when taking into account the practice of multinational pharmaceutical companies which usually make their products available in the markets of developing countries with much higher prices than anywhere else in the world.

It is also important to say that Law 9279/96, considered the insertion of the country in the process of economic liberalisation of world trade. The drafters of Law 9279/96 have undoubtedly considered that the application of the principle of international exhaustion of IPRs will affect also products patented, manufactured and marketed in Brazil.

1.3. The negotiations in the MERCOSUL

While the issues related to the protection of intellectual property rights are a matter for national jurisdiction based on the application of the national sovereign rights, this is broadened by the prospect of an integrated market in which goods circulate free of any type of barriers.

The Treaty of Asuncion affirms in Article 1 that the MERCOSUL shall be based on the "[f]ree movement of goods, services and factors of production between countries through, *inter alia*, the elimination of customs duties and non-tariff restrictions on the movement of goods, and any other equivalent measures".

As far as the granting of IPRs is essentially a national measure, the application of these rights are limited to national boundaries and may be used as restrictions having effect on the free circulation of goods throughout the territories of the States Parties.

Estrella Faria affirms that the establishment of the principle of free movement of goods is dependent on two major groups of rules: "a programme of tariff reductions and the principle of national treatment, on the one hand, and the prohibition of quantitative restrictions[17] and measures having equivalent effect, on the other"[18].

Estrella Faria also affirms that three regulatory aspects must be included in this discussion: tariff reductions and national treatment, the elimination of non-tariff barriers and safeguard clauses. The issues which will come out from this discussion and which are related to the territorial applicability of IPRs in the territory of the MERCOSUL are essentially the third aspect, *i.e.* the elimination of non-tariff barriers among the participating countries.

In connection with the application of the international exhaustion of rights principle, the current legislation of the four countries of the MERCOSUL does not deal expressly with the subject. The WIPO Proposal has nevertheless suggested that the rights over a patent do not include the right to impede a third person to use a patented product commercially after it has been introduced to the market of any State Party of the MERCOSUL by the patent holder or by someone with the patentee's consent or economically linked to him[19]. The WIPO Proposal suggested the application of the general principle of regional exhaustion of rights, but left open the doubtful question of the meaning of a economically linked person in this context.

---

[17]Treaty of Asuncion, Annex I (Trade Liberalisation Programme), Article 2 (b), defines the term "restrictions" as such: "'Restrictions' shall mean any administrative, financial, foreign exchange or other measures by which a State Party unilaterally prevents or impedes reciprocal trade".

[18]**José Ângelo Estrella Faria**, O MERCOSUL: Princípios, Finalidades e Alcance do Tratado de Assunção, Brasília: MRE/SGIE/NAT (1993), p. 76.

The Brazilian Proposal has also suggested that the rights conferred by a patent do not include a "manufactured product in relation to a patent of process or product which has been put into the internal market or in any State Party directly by the patent holder or with his consent"[20].

It does not seem that the issues on exhaustion of patent rights are controversial in the current stage of negotiations in the MERCOSUL. States Parties know that the rights over a patent will be exhausted somehow by virtue of the application of the principle of free circulation of goods, after the product has been lawfully put into the market in the territory of the MERCOSUL. What seems to be lacking so far is the application of the general principle in the context of the disputes that may come up. Considering the experience of the EC the application of this principle is not necessarily an easy task. Several situations, with different economic, commercial and legal characteristics, will occur at some stage. National juridical understanding will have to be harmonised for the effective application of this principle as a means of ensuring the proper operation and functioning of the integrated area of the MERCOSUL. This may be done in a limited basis through the institutional mechanisms established by the Ouro Preto Protocol[21].

---

[19]WIPO Proposal, Art. 13 (1). In paragraph 2, Article 13, says that the expression "someone economically linked with the patent holder" should be understood as someone who may perform, directly or indirectly, a decisive influence in respect with the exploitation of the patent.
[20]Brazilian Proposal, Item 5.1. (IV).
[21]*Cf.* Chapter 1, Section 2, Sub-section 2.3, Paragraph 2.3.1, *supra*.

2. COMPETITION LAW

The concept of competition law has been developed, in accordance with Gabriel Leonardos[22], based on two particular types of rights and obligations: antitrust laws and unfair competition laws.

In accordance with Gabriel Leonardos, antitrust laws' aim is the assurance of free competition, by the imposition of fines and sanctions against its infringer, and is part of what may be called "Criminal Economic Law". It is assumed that the concept of antitrust law emerged in the United Kingdom in 1410 by juridical developments in the national courts and that the first legal mechanism setting up measures to regulate antitrust law principles was provided in Germany, on 27 May 1896.[23]

Unfair competition law, on the other hand, regulates the activities of undertakings in a particular market, making sure that their actions do not establish a unfair market for other competitors. This concept is part of industrial property law principles. It is assumed that the concept of unfair competition emerged in France in 1850 based on decisions from national courts[24], and was finally established as a legal mechanism in the 1900 revision of the Paris Convention.[25]

In the context of a free market economy, a set of legal norms or juridical understanding is usually established to regulate and control the commercial practice of undertakings. This is necessary not only to prevent the honest competitor from unfair

---

[22]**Gabriel Francisco Leonardos**, A Relação entre o Direito Antitruste e o Direito da Propriedade Industrial, paper presented during the 16th National Seminar of Industrial Property, São Paulo, Brazil, 20 August 1996.

[23]**Hermano Duval**, Concorrência Desleal, São Paulo: Editora Saraiva S.A. (1976), at p. 124.

[24]**WIPO**, Protection Against Unfair Competition, Geneva: WIPO (1994), pp. 15-17, paras. 12-17.

[25]For further discussion on Article 10*bis* of the Paris Convention, which is the provision dealing particularly with the protection against unfair competition, see Paragraph 2.1.1., *infra*.

business practices, but also to ensure that the consumer will benefit from the competitive market - generally with lower prices and higher quality products - and that the market itself will not be distorted by anti-competitive practices of undertakings.

It is also possible to affirm that, in theory, the market itself could regulate the practices of undertakings within a territorial limit, through the approach taken by the consumers themselves towards the products which have been offered to them by both honest and dishonest undertakings. In practice, however, self regulation mechanisms to ensure that competition takes place in the market, and that consumers have direct benefits from that does not seem viable.[26]

Additionally, when one links competitive practices with the rights conferred by a patent, the situation becomes more complex. Generally speaking, a bundle of mechanisms is granted to the patent holder allowing him to use juridical or administrative tools to prevent others from infringing the temporary exclusive rights which have been granted to him by the State. These legal mechanisms are often provided by national industrial property laws and are more closely related to the use of legal measures against the infringement of the patentee's rights to exploit his patented invention. Sometimes, however, industrial property regulations are not exhaustive in relation to the protection against anti-competitive practices by right holders.

---

[26]**WIPO**, note 24, *supra*, pp. 11-12, para 6-8. In fact, as highlighted by this WIPO study, in paragraph 6, "[a]s an economic situation becomes more complex, consumers become less able to act as referees. Often they are not even in a position to detect by themselves acts of unfair competition, let alone react accordingly. Indeed it is the consumer who - along with the honest competitor - has to be protected against unfair competition".

One should bear in mind that not only should the practices of third parties against the rights conferred upon the patentee be regulated, but also the practices of the patentee himself when using and exploiting his temporary rights. In relation to the exploitation of patent rights, therefore, two general practices will need to be controlled: the acts against the right conferred upon the patent holder and the acts of the patent holder himself, when using, licensing or assigning his rights.

It is generally established that the patentee has the exclusive right to impede acts carried out by someone else without his consent which relates to the manufacturing, storing, selling, offering for sale, importing or exporting of his patented product. National industrial property regulations usually provide mechanisms which may be used by the patentee to prevent such practices as a means of protecting his individual rights. This may happen in different situations which will be discussed throughout the present Section.

It is also necessary to consider that there are the acts which distort competition in a specific market, against the public interest. These practices are usually related to the patentee's right to license or assign his rights which in some cases may create a situation which is unlawful. In Chapter 3, for instance, these acts have been discussed in more detail when related to licensing agreements in the EC.

Industrial property laws that regulate unfair competition are also complemented by specific rules on protection against unfair competition, as well as by juridical understandings of the national courts. Firstly, it is necessary to point out that national legislation containing the rules regulating the commercial practices of undertakings are used to complement the provisions included in national industrial property laws which are related to anti-competitive acts arising from an intellectual

property right. A GATT study found out that the type of legislation generally used to regulate competitive practices, in connection with intellectual property protection, is intellectual property, competition and transfer of technology laws[27]. Industrial property and competition laws, in principle, "... deal with matters arising from the use, licensing and assignment of any IPR, ... only technology-related IPRs are normally dealt with the transfer of technology legislation"[28].

Additionally, pure competition laws will be assessed taking into account that "... the basic criteria generally employed are whether a practice restricts, distorts or prevents competition or the free movement of goods in the market-place, or whether there is an abuse of a dominant market position"[29]. The basic criteria to assess a competitive practice in connection with a technology-related intellectual property right, through transfer of technology regulations, are generally provided for transactions between a foreign provider of technology and a local party in the acquiring country. These regulations will thus "... seek to ascertain whether certain wider interests related to the economic and technological development of the technology-receiving country are being served, in particular whether technology is being transferred to the country on reasonable conditions"[30].

In relation to the building up of juridical understanding of national provisions on the protection against unfair competition, it is necessary to recall that national courts will decide upon a specific dispute and judge whether or not a specific act is against national legal provisions. National courts may nevertheless develop further

---

[27]GATT Doc. N. MTN.GNG/NG11/W/64 (1 February 1990) National Legislation and Practices Deemed Restrictive in Connection with Intellectual Property Rights, Note by the Secretariat, p. 1, para. 3

[28]*Ibid.*, para. 5 (ii), p. 3.

understanding on the interpretation of the law. Their rulings will then establish the juridical approach towards a national legal framework for industrial property protection, broadening the interpretation of industrial property, competition and transfer of technology regulations.

This Section discusses the subject considering the international legal framework, in particular the Paris Convention and the TRIPS Agreement, national legislation and current legislative developments in Brazil and the negotiations in the MERCOSUL.

2.1. International legislation

The regulation of anti-competitive practices in the international arena was first recognised by the Brussels Diplomatic Conference for the Revision of the Paris Convention in 1900, with the inclusion of Article 10*bis* into the text of the Paris Convention[31]. When the Paris Convention first recognised that competition rules should be regulated in relation to industrial property protection, Article 10*bis* stated that national laws regulating unfair competition should be applied to nationals of other Members of the Paris Union, only considering the application of the national treatment principle to foreign competitors[32].

Moreover, and taking into account the developments of international industrial property laws, the TRIPS Agreement has also considered the issues on measures

---

[29]*Ibid.*, para. 6, p. 3.
[30]*Ibid.*, para. 7, p. 3.
[31]See, *e.g.*, **WIPO**, note 24, *supra*, p. 9.
[32]The first version of Article 10*bis* stated that "[n]ationals of the Convention (Articles 2 and 3) shall enjoy, in all the States of the Union, the protection granted to nationals against unfair competition" (as quoted in **WIPO**, note 24, *supra*).

against unfair competition on a limited basis. The following is an analysis of the issues in both international instruments.

2.1.1. The Paris Convention

Initially, the Paris Convention in Article 1 (2) determines that along with patents, utility models, industrial designs, trade-marks, service marks, trade names, and indications of source or appellations of origin, the protection of industrial property, as thereby provided, includes the repression of unfair competition. The purpose of this provision is only to determine that the repression of unfair competition is also the subject-matter of industrial property protection.

After being subject to several modifications drawn up by the subsequent revisions of the Paris Convention, Article 10*bis*, which deals in more detail with the rules on the repression of unfair competition, currently reads as follows:

> (1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.
> (2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.
> (3) The following in particular shall be prohibited:
> 1. all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;
> 2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;
> 3. indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

The Paris Convention firstly sets up in Article 10*bis* (1) a general obligation. Members of the Paris Union are therefore requested to make effective protection

against unfair competition under their national laws or jurisprudence. As highlighted by the WIPO[33], this may be done by the enactment of specific legislation on protection against unfair competition, by including specific provisions within broader statutes, by the application of general tort provisions or by a combination of civil principles, case law and specific laws[34].

Alongside Article 10*bis* (1), Article 10*ter* of the Paris Convention states that legal remedies must be available to assure protection against unfair competition, in particular those "... to permit federations and associations representing interested industrialists, producers, or merchants, ..."[35] to undertake measures allowing them protection against acts of unfair competition.

According to Article 10*bis* (2), Paris Convention, acts of unfair competition are those contrary to honest practices in industrial or commercial matters. In this connection, it is worth noting that the Paris Convention leaves a great degree of discretion to Members of the Paris Union to interpret and define further what shall be considered an act contrary to honest practices. It is possible to assume that national legislation, together with the approach taken by national courts and administrative authorities, will attempt to limit the application of such term. It is clear that this is a general and broad concept which must be developed further by national authorities.

---

[33]Note 24, *supra*, pp. 20-22.
[34]Accordingly, the WIPO study, note 24, *supra*, emphasises in paragraph 26, p. 21, that most of the Members of the Paris Union use a combination of all the systems referred to.
[35]Paris Convention, Art. 10*ter* (2).

As pointed out by the WIPO study[36], a reference has to be made in connection with the subjective element of an act which is unfair or dishonest. In this sense, WIPO states the following:

> At first sight, the notion of "honesty" seems to refer to a moral standard, and some sort of "legal/ethical standard" is indeed involved. This, however, has to be distinguished from the question whether an act of unfair competition can be established in the absence of any fault, bad faith or negligence. Where unfair competition law has been developed on the basis of general tort provisions [for instance], the "tort of unfair competition" requires some kind of subjective element such as "fault" or "bad faith". In practice, however, the element of fault or bad faith is often assumed by the courts. Such subjective elements are therefore not essential to the notion of fairness in competition.

The above quotation seems to be limited in essence. Not only national courts will play the role of defining the limits and boundaries of the subjective element of an act which is to be considered in connection with the competitive practices of honest competitors or against the consumers or the public interest in general. Administrative authorities may also play a very important role in this context. In addition, it is important to note that some degree of interpretation of an act which involves "fault, bad faith or negligence" is to be developed by national legislation.

An example of what has been said in the foregoing paragraph is the list of acts which are against fair competition, provided by Article 10*bis* (3) of the Paris Convention. In a minimum basis, and indeed non-exhaustively, the Paris Convention determines that all acts which aim to create confusion[37], and false allegations in the

---

[36]Note 24, *supra*, para. 32, p. 24.
[37]Paris Convention, Art. 10*bis* (1) (1).

course of trade[38], in relation to the establishment, the goods or the commercial or industrial activities of a competitor, will be prohibited by national legislation. Although these acts are directly related to the infringement of trade-marks or trade names, it is possible that a patented product, bearing a particular mark and produced by a specific competitor, will fall within the wording of Articles 10*bis* (3) (1) and (2).

Article 10*bis* (3) (3) states that any indications or allegations which in the course of trade could mislead the public as to the nature, the manufacturing process, the characteristics, the suitability or the quantity of goods shall be also prohibited. Again the goods in question, or the manufacturing process which is used, may relate to a patented product.

2.1.2. The TRIPS Agreement

During the TRIPS negotiations discussions on the protection of competition divided developed and developing countries. On the one hand developed countries generally suggested that the provisions on protection against unfair competition should deal only with the disclosure of proprietary information, *i.e.* trade secrets[39]. Developing countries, on the other hand, pushed for more effective rules in the field of

---

[38]*Ibid.*, Art. 10*bis* (1) (2).

[39]See, *e.g.*, the opinion of the European Community (GATT Doc. N. MTN.GNG/NG11/W/68 (29 March 1990) Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 28, pp. 12-13), of the United States (GATT Doc. N. MTN.GNG/NG11/W/70 (11 May 1990) Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, Communication from the United States, Art. 31, p. 13), and of Switzerland (GATT Doc. N. MTN.GNG/NG11/W/73 (14 May 1990) Draft Amendment to the General Agreement on Tariffs and Trade on the Protection of Trade-Related Intellectual Property Rights, Communication from Switzerland, Art. 241, p. 17).

competition law, explicitly opposing the inclusion of trade secrets in the TRIPS negotiations[40].

The position of developed countries is well expressed in the Japanese proposal[41] where it was affirmed that "[f]or the purpose of protecting domestic industries, a certain number of governments put licensing of intellectual property rights under their authorization, and lay down various restrictions on licensing agreements made between enterprises of industrialized countries and ones of the countries in question"[42].

The Japanese statement clearly leads one to think that those "countries in question" are some developing countries. What may be generally understood from this is that administrative authorities of developing countries tend to control and limit the application of licensing contracts. Developing countries are primarily importers of technology and, in my opinion, it is advisable that licensing agreements between the provider of technology and its receiver should be controlled by national governments, as a means of setting up the necessary limits to licensing agreements and of guaranteeing that technology transfer will take place in a fair manner.[43]

---

[40]The argument of developing countries was that trade secrets were not regarded as IPRs, thus not within the mandate of the Uruguay Round of negotiations. See, for example, the opinion of Peru, Brazil and India in GATT Doc. N. MTN.GNG/NG11/W/32/Rev.2 (2 February 1990) Synoptic Tables Setting Out Existing International Standards and Proposed Standards and Principles, p.121.

[41]GATT Doc. N. MTN.GNG/NG11/W/7 (29 May 1987) Submissions from Participants on Trade Problems Encountered in Connection with Intellectual Property Rights, p. 17.

[42]See also, for similar argument, the opinion of Canada in GATT Doc. N. MTN.GNG/NG11/W/47 (25 October 1989) Standards for Trade-Related Intellectual Property Rights, Submission from Canada, para. 6, pp. 2-3.

[43]It seems that even the debate among developed countries was not entirely settled. The EC, for instance, has yielded to the need for more detailed provisions to avoid the abusive use of IPRs, in accordance with the law and practices of the European Common Market itself (GATT Doc. N. MTN.GNG/NG11/W/15 (20 November 1987) Guidelines Proposed by the European Community for the Negotiations on Trade-Related Aspects of Intellectual Property Rights, p. 3).

In opposition to that, "[a] number of participants have referred to conditions in licensing agreements which are abusive or anti-competitive and thereby represent unwarranted restrictions on international trade in goods"[44]. Such statement is entirely based on the position taken by a group of developing countries. A joint proposal submitted to the TRIPS negotiations highlighted two points in connection with competition law, which represents the opinion of developing nations. Firstly, it was suggested that parties should co-operate with each other to ensure that goods would circulate freely and that IPRs would not be used to create restrictions or distortions to international trade or to engage in anti-competitive practices which would have adverse effects on trade[45]. Secondly, there was a proposal that national legislation should specify which practices would constitute an abuse of an intellectual property right in connection with licensing contracts[46].

The position of developing countries was more detailed than that of developed countries. They have not, however, tried to establish how national authorities should deal with the concept of abusive use of IPRs, nor have they suggested which clauses in a licensing agreement should be considered as anti-competitive. It is possible to assume that developing nations wished to have a broad concept in the text of the TRIPS Agreement which would leave discretion for the setting up of more detailed rules on this matter to national authorities and national courts.

The concluded text of the TRIPS Agreement has indeed included some of the suggestions of developed and of developing countries. The final text contains three

---

[44]GATT Doc. N. MTN.GNG/NG11/W/12/Rev.1 (5 February 1988) Compilation of Written Submissions and Oral Statements, Prepared by the Secretariat, Revision, para. 85, p. 30.
[45]GATT Doc. N. MTN.GNG/NG11/W/71 (14 May 1990) Communication from Argentina, Brazil, Chile, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, Art. 5, p. 4.

provisions dealing with protection against unfair competition. Two are likely to be the result of the initiative of developing countries, dealing specifically with matters on competition law[47]. The third provision is very much a proposal of developed nations and relates to the protection of trade secrets or undisclosed information[48].

Article 8 (2) of the TRIPS Agreement accepts that "[a]ppropriate measures, ..., may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology". This provision, though not mandatory, appears to be a very important step towards fairer rules on the transfer of technology and, above all, a recognition of the needs of technologically poor nations. It is in the interest of developing nations to have just and fair terms in technology transfer agreements enabling these countries to develop their own technological capabilities. The TRIPS Agreement has thus accepted that national legislation could establish appropriate rules governing agreements which include the transfer of technology, aiming to promote the exchange of technology between North and South. It also recognises that national legal measures may be necessary in some circumstances to avoid practices which would constitute an abuse of an intellectual property right, therefore creating adverse effects on international trade. This provision will not apply, however, if the conditions established by national regulations are contrary to the provisions of the TRIPS Agreement.

In addition to the general principle established by Article 8 (2), Article 40 (1) of the TRIPS Agreement affirms that "Members agree that some licensing practices or

---

[46]*Ibid.*, Art. 15, p. 11.
[47]TRIPS Agreement, Arts. 8 (2) and 40.

conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology". Members of the WTO Agreement are therefore allowed to specify in their national legislation which licensing practices and conditions should be considered an abuse of an intellectual property right or an anti-competitive practice. As a consequence, Article 40 (2), TRIPS Agreement, affirms that a "Member may adopt, consistently with the provisions of this [TRIPS] Agreement, appropriate measures to prevent or control such practices, ...". Paragraph 2 of Article 40 also provides for a non-exhaustive list of examples which may be regarded as anti-competitive[49].

Article 40, TRIPS Agreement, suggests a consultation mechanism between two countries when an anti-competitive practice by an undertaking of one of the countries in question takes place. When an undertaking acts against competition rules or abuses its IPRs in a particular country, the latter country shall enter into consultation, upon request, with the country in which the undertaking is a national or domiciled, without prejudice to any action under the law of the country whose rules have been breached. The addressed country shall, therefore, co-operate by supplying publicly available non-confidential information or other information which could be relevant to assess the anti-competitive condition of such undertaking. The country which received such information must, however, safeguard the confidentiality of the information which has been provided.[50]

---

[48]*Ibid.*, Art. 39.

[49]The examples provided by Article 40 (2), TRIPS Agreement, are exclusive grant-back clauses, no-challenge clause and coercive package licensing.

[50]TRIPS Agreement, Art. 40 (3).

Additionally, if a country whose nationals or domiciliaries are subject to proceedings in another country in relation with violation of the other country's laws and regulations, the first country may also request consultations under the same conditions of Article 40 (3) of the TRIPS Agreement[51].

Apparently, the intention of the negotiators, when drafting such provisions, was that national proceedings concerning anti-competitive or abusive practices could be hastened if information from the domiciliary country can be provided and, in addition, misunderstandings and future disputes between Members of the WTO Agreement could be avoided. In practice, however, if one considers the several circumstances in which a breach of competition law may take place and the nature of such acts, it is possible to predict that such consultative proceedings are likely to have very limited effect.

In addition to the provisions directly addressing anti-competitive practices, the TRIPS Agreement has accepted the suggestion of developed countries and included the protection of trade secrets, under the heading "Protection of Undisclosed Information". Article 39 (1), TRIPS Agreement, says that, taking into consideration the wording of Article 10*bis* of the Paris Convention, and aiming to ensure protection against unfair competition, Members of the WTO Agreement shall protect undisclosed information[52], and data which has been submitted to government authorities, when such data is required for the purposes of approving the marketing of pharmaceutical or agricultural chemical products[53].

---

[51] *Ibid.*, Art. 40 (4).
[52] *Ibid.*, Art. 39 (2).
[53] *Ibid.*, Art. 39 (3).

2.2. The legislation in Brazil

The legal mechanism for the protection of acts against unfair competition was first recognised in Brazil by Decree N. 11.385, of 16 December 1914, which is the legal instrument on the ratification of the Paris Convention. It was included in the national legal framework, however, only after the publication of Decree N. 24.507, of 29 July 1934. The general principle established by the original wording of the Paris Convention and improved by the revision of the Paris Convention in the Hague, in 1925, promulgated in Brazil by Decree N. 19.056, of 31 December 1929, has not been of practical effect, because until the publication of Decree 24.507/34 the mechanism for the protection of competition was completely ignored in Brazil. Later, Decree-Law N. 7.903, of 27 August 1945, provided for a more detailed understanding on this matter.

Modern legislation in Brazil has taken into account international developments and Brazilian policy towards an open market. This Sub-section analyses the subject considering several national constitutional and ordinary provisions, both in the field of industrial property and in the field of competition law.

2.2.1. The constitutional basis

Protection against unfair competition is the subject of two constitutional provisions in Brazil. First, the Brazilian Constitution, in Article 170 (IV), establishes that the Brazilian economic order is based on, *inter alia*, the principle of free competition. This principle, which is intended to ensure that a healthy competitive approach

prevails in the Brazilian market, is further considered in Article 173 (4) which says that "[t]he law shall repress abuse of economic power seeking to dominate markets, to eliminate competition and to increase profits arbitrarily".

Following an analysis of the provisions above quoted, it is possible to affirm that the Brazilian Federal Constitution initially recognises the existence of economic power in market forces, which will be prohibited or condemned by the constitutional principles once exercised in a manner against honest practices. What will be prohibited, by virtue of Article 173 (4), is the exercise of this economic power which may eventually be anti-social and, consequently, anti-economic[54]. This behaviour will be regulated by national ordinary legislation, based on constitutional principles.

It is important to note that two different approaches have been taken to protect the Brazilian market against the dishonest commercial practices of competitors. Firstly, the Brazilian constitution recognises in Article 170 (IV) that free competition will be one of the principles which shall prevail in the Brazilian economic order. That is because the intention of the national legislature, gathered as a "Constitutional Convention" from 1985 to 1988, was to establish a new order for the application of the economic, commercial and social principles of the new period of redemocratisation of Brazil.

Secondly, aiming at the appropriate regulations which will control and limit these practices, the Brazilian Constitution has understood that some undertakings may exercise this economic power in ways which will not be acceptable. The detailed regulation of commercial practices will be established by national ordinary legislation

---

[54]**José Afonso da Silva**, Curso de Direito Constitucional Positivo, São Paulo: Editora Revista dos Tribunais (1991), 7th ed., p. 666.

that will formally repress the abuse of economic power which seeks to dominate the market, to eliminate competition or to increase profits arbitrarily. This may be done by applying a single set of rules or by using a bundle of legal provisions, as included in different laws. The constitutional provision in question recognises that some practices which constitute an abuse of economic power may distort the free market, thus being against the principle of free competition. Therefore, the constitutional rule will be breached if the commercial practice of a particular company distorts the market by abusing its economic power. Not only the actual practice of a particular undertaking, but also the mere existence of a dominant position seeking abusive dominance of markets or the distortion of competition will be prohibited. National ordinary legislation, however, will have the task of regulating this matter in more detail.

Some authors, particularly José Afonso da Silva[55], understand nevertheless that the way in which the modern world has developed has made anti-competition laws an ineffective regulation when put into practice. He says:

> What is necessary to recognise, in fact, is that there is no longer economic market nor free competition, since capitalist production developed to oligopolistic forms. To talk today about decentralised economy, as market economy, is to try to hide a reality of divers
>
> e nature.[56]

The author seems to emphasise that in the capitalist world market behaviour is based on large gatherings of companies, through mergers and other practices, which, in one way or another, makes legislation in favour of competition rather ineffective. It is true that in such a world some difficulties arise when one attempts to control and

---

[55] *Ibid.*

limit the competitive practices of large undertakings which are dominating the markets on a global basis. However, it is necessary to bear in mind that different regulations will be made necessary to regulate commercial practices in three levels of application and jurisdiction: international, regional and national.

The international level is regulated by the rules of international organisations, particularly that of the former GATT, now the WTO. GATT's troublesome origins transformed its rules in a confuse form of international organisation[57]. Nowadays, the WTO seems to be leading the multilateral process of liberalisation international trade - or, somehow, confirming its historical leadership - with the approval of the Final Act as a result of the Uruguay Round of negotiations. The WTO system was provided with a rather broad framework of principles for international trade and with a more pragmatic method to resolve disputes.

In the regional level, the EC experience is a major modern example that would be taken into consideration. The EC showed that a process of political, economic and commercial approximation of countries could be supported by the principles of of free movement of goods, persons, services and capital. As a consequence of the application of these principles, competition law appears to be a necessary approach towards regional control of market behaviour and activities. The problem which arises in this situation is that in the context of an integrated area there should be a minimum degree of unification of national competition law principles and, above all, a unified method to enforce competition norms. The latter need will be fulfilled only by some

---

[56] *Ibid.*, pp. 666-667.
[57] *Cf.* Chapter 2, Section 2, *supra*.

degree of transference of national sovereign rights to a regional institution with supra-national powers.

In the national level, the application and enforcement of competition rules differ in substance from the two other levels discussed above. Generally speaking, States have their own administrative, legislative and juridical structure to deal with several aspects of law and society. This structure, fully (and most of the times) recognised as sovereign, makes legislative process, management and application of competition rules more feasible.

2.2.2. As in industrial property laws

The crimes against unfair competition were originally established, in connection with the protection of intellectual property, by Article 196 of Decree-Law N. 2.948, of 7 December 1940, the Penal Code. This provision was then revoked and substituted by Article 178 of Decree-Law N. 7.093, of 27 August 1945 (Decree-Law 7093/45), which was an early version of the CPI. The CPI has, in Article 128, established that the early provisions of Decree-Law 7093/45, in particular Article 178, would apply until Decree-Law N. 1.004, of 21 October 1969, came into effect. The latter, however, has never entered into force, which makes Article 178 of Decree-Law 7093/45 the legislation still in force under the Brazilian legal framework.

Article 178 of Decree-Law 7093/45 may be divided into two main branches. First, Article 178 deals directly with the type of crimes constituting an act of unfair competition, described by Article 178 (I) to (XII) that lists twelve crimes. Second, one finds the acts of unlawful competition giving rise to civil protection by way of damages which may eventually be paid to the honest competitor. This type of legal

mechanism is provided only by Sole Paragraph of Article 178, aiming at broadening the limited approach taken by Article 178 (I) to (XII). The differences between the two approaches will be discussed below, followed by the new provisions of Law 9279/96.

Article 178 affirms that a crime against unfair competition law[58] will arise in the following circumstances: publication in the press, or by other means, of a false declaration against a competitor, aiming at gaining advantage from the latter[59]; dissemination of false information about a competitor, causing losses to the latter[60]; use of unlawful means to take away clients of a competitor[61]; manufacture, import, export, storing, selling or offering to sell goods with false indications of origin[62]; use on the label of a product of terms which would induce the consumer to think that the product in question is related to a product which is manufactured and/or sold by another undertaking[63]; substitution for one's own business or natural name of the current name of a product which has not been produced by him, without the consent of the real producer of the product with that name[64]; using, as means of industrial or commercial publicity, of distinctions that have not been given to him[65]; selling or offering for sale counterfeit goods in the package of another product[66]; giving or offering money or other benefits to the employee of a competitor, aiming at unlawful

---

[58] *Cf.* CPI, Art. 2 (d).
[59] Decree-Law 7093/45, Art. 178 (I).
[60] *Ibid.*, Art. 178 (II).
[61] *Ibid.*, Art. 178 (III).
[62] *Ibid.*, Art. 178 (IV). *Cf.* CPI, Arts. 65 (9) and (10), 66 (trade-marks) and 70 (certificate of origin).
[63] *Ibid.*, Art. 178 (V). *Cf.* CPI, Arts. 65 (9) and (10), 66 (trade-marks) and 70 (certificate of origin).
[64] *Ibid.*, Art. 178 (VI). *Cf.* CPI, Art. 119.
[65] *Ibid.*, Art. 178 (VII). *Cf.* CPI, Art. 119.
[66] *Ibid.*, Art. 178 (VIII).

advantages[67]; and divulging or exploiting, without authorisation and when employed by someone, trade secrets of the latter which have been disclosed under the terms of the employment agreement[68]. The penalties for all the crimes above listed are imprisonment from three to twelve months, or fines.[69]

Article 178, Sole Paragraph of Decree-Law 7093/45, also provides for what has been called unlawful competition. This provision considers that the crimes listed in Article 178 (I) to (XII) do not preclude civil actions for losses and damage which may have occurred as a consequence of the practices above listed. Decree-Law 7093/45 has taken into account that the criminal sanctions available are not sufficient and that damage or losses to the honest competitor may occur in those situations. It is therefore understood that once there is a juridical ruling concerning the crime which has been committed by someone, the competitor who has suffered from that practice may automatically claim his civil rights in connection with the damage and losses that he has suffered[70]. This juridical civil action, which follows the criminal action, is limited to the *quantum* of losses and damages[71]. Hermano Duval affirms that in most cases, breach of the rules against unfair competition is more a civil matter, where damage and losses have to be assessed, than one of criminal sanctions. The honest competitor who has suffered from the practices of a dishonest one will probably be

---

[67] *Ibid.*, Art. 178 (IX). On the other hand, it is understood as a crime against unfair competition to accept money or other benefits against the disclosure of information which will give unlawful advantage to a competitor of the employer (*Ibid.*, Art. 178 (X)).

[68] *Ibid.*, Art. 178 (XI). This will apply even after the employment agreement has finished (*Ibid.*, Art. 178 (XII)). *Cf.* TRIPS Agreement, Art. 39.

[69] *Cf.* Decree-Law 7.093/45, Arts. 169 to 174 for a list of crimes against patent, utility model, industrial model and industrial design.

[70] Civil Code, Art. 1.525 and Civil Proceedings Code, Art. 63.

[71] **Hermano Duval**, note 23, *supra*, at p. 226.

more keen to receive the appropriate compensations for the damage which has been caused to him rather than seeing his competitor in jail[72].

The negotiations in the Brazilian Parliament have considered, during the discussions of Law 9279/96, the inclusion of provisions dealing directly with crimes against unfair competition. Article 195 of Law 9279/96 considers the subject exactly as it has been analysed in the Decree-Law 7093/45, but does not include the distinction between unlawful and unfair competition. Such a distinction has not been included possibly because the general principles of civil law for the protection of honest competitors against damage or losses would apply collaterally.

In addition. Article 195 (2), Law 9279/96, determines that when the government divulges, without authorisation, the results of tests or other data submitted to the government for the purpose of market approval, in order to protect the public, this will not be considered against the unfair competition.

2.2.3. As in competition law

Law N. 8884, of 11 June 1994[73], says that any acts aiming at or with the possibility of causing the following effects, shall be considered an infringement of the national economic order: to limit or, by any form, cause damage to free competition or the free market; to dominate a relevant market of goods or services or the abuse of a dominant position[74]; or to raise profits arbitrarily[75].[76]

---

[72] *Ibid.*

[73] Hereinafter "Law 8884/94".

[74] Law 8884/94 considers that a dominant position exists when an undertaking or a group of undertakings controls a substantial part of a relevant market, either as a supplier, buyer or intermediate agent, or sponsor of a product, service or technology (*Ibid.*, Art. 20 (2)). A substantial part of the relevant market occurs when it reaches 30% of that specific market (*Ibid.*, Art. 20 (3)). It is necessary to mention that when an undertaking or a group of undertakings reach the dominant

Additionally, the following acts, among others, if within the conditions listed in the foregoing paragraph, will be considered an infringement of the economic order: concerted practices among competitors; the partition of markets of services or products; to limit or impede access of other undertakings to the market; to create difficulties for the establishment of other undertakings; to hinder access for competitors to raw materials, technology equipment or distribution mechanisms; to demand or give exclusivity for advertisement in any form of communication; to regulate goods and services markets by the establishment of agreements to limit or control research and technological development; to monopolise or impede the exploitation of intellectual property or of technology; to sell goods below the production price; and to impose excessive prices or to raise prices without justification.[77]

Those who act against the economic order, as above described, will be subject to penalties. An undertaking, for instance, will be liable to pay a fine from 1 to 30% of its total turnover in the last fiscal year[78]. In the case of a manager who is responsible directly or indirectly for the violation of the economic order by his company, he will have to pay a fine of 10 to 50% of the fine imposed upon the undertaking in question, but such a fine is the exclusive and individual responsibility of the manager[79].

---

position by efficiency, it will not be considered as a violation of the economic order (*Ibid.*, Art. 20 (1)).

[75]Law 8884/94, Art. 20 (I) to (IV).

[76]These provisions will apply to natural or legal persons, of private or public character, and the responsibilities upon the acts referred to in Article 20 (I) to (IV) of the Law 8884/94, are of the undertaking in question and of its directors or managers (*Ibid.*, Arts. 15 and 16).

[77]*Ibid.*, Art. 21.

[78]*Ibid.*, Art. 23 (I).

[79]*Ibid.*, Art. 23 (II).

Other penalties may be imposed upon an undertaking, cumulatively to those described in the paragraph above. These additional penalties include the publication of the decision of the Administrative Council for Economic Protection (CADE), paid by the violating undertaking, in a newspaper indicated in the decision, for two consecutive days, from one to three consecutive weeks[80]. Other penalties may be imposed under the terms above described, such as the prohibition of the undertaking from making commercial agreements with public undertakings, or even the recommendation of the granting of a compulsory licence to the product of the violating company[81].

For the assessment of the appropriate penalty, the following aspects or circumstances shall be considered: the seriousness of the infringement; the goodwill of the violator; the advantage reached or aimed at by the violator, and in this situation whether or not he reached the advantage; the degree of damage, or the threat of damaging the national economic order, the free competition rules, and consumers or other competitors; the negative economic effects on the market; the economic situation of the violator; and the contumacy or eventual continuous disobedience of the violator.[82]

The institutional mechanism designed to regulate competitive practices in the Brazilian Market was, until recently, based on the CADE, as included in the institutional framework of the Council of Ministers[83]. By virtue of Law 8884/94 the CADE was transformed in a federal government agency and its powers were

---

[80] *Ibid.*, Art. 24 (I).
[81] *Ibid.*, Art. 24 (II) and (IV) (a), respectively.
[82] *Ibid.*, Art. 27.
[83] Law N. 4.137, of 10 September 1962.

extended. This paragraph will consider only the provisions and institutional framework as in Law 8884/94.

The CADE is composed by a President and six Counsellors appointed by the President of Brazil and approved by the Federal Senate[84], for a renewable mandate of two years[85]. The President of CADE is empowered *inter alia* to represent the organisation; to preside and vote in its plenary meetings; to distribute to one of the Counsellors administrative proceedings relating to competitive practices; to request the enforcement of the decisions of the plenary; and to sign all the commitments related with the administrative proceedings analysed by the organisation[86].

The Counsellors, on the other hand, are empowered to vote for the decisions of the plenary of CADE; to report on the processes that are distributed to them; to submit to the plenary session of CADE request of information from anyone, including public and private entities; to adopt interim measures and penalties related to the non-fulfilment of the decisions of the plenary of CADE; and to perform other duties conferred to him by the Rules of Procedures of CADE[87].

The Plenary of CADE must perform, *inter alia*, the following duties: to decide upon the existence of a violation of the economic order and to impose the respective penalties; to decide upon the processes initiated by the Secretary of Economic Law of the Ministry of Justice (SDE)[88]; to establish the necessary measures for the

---

[84]Law 8884/94, Art. 4, *caput*. The President and the Counsellors of CADE will be chosen among Brazilian citizens with more than thirty and less than 65 years with recognised legal or economic knowledge.
[85]*Ibid.*, Art. 4 (1).
[86]*Ibid.*, Art. 8.
[87]*Ibid.*, Art. 9.
[88]The SDE is headed by a Secretary appointed by the Minister of Justice and has the following functions: to follow, permanently, the commercial practices and activities of natural or legal persons who are in a dominant position; to carry on preliminary investigations for the setting up of

interruption of the violation of competition rules; to decide upon appeals; to request information from anyone, either natural or legal entities; to request the Judiciary to enforce decisions taken by the plenary of CADE; and to inform the public about the various forms of infringement of the economic order.[89]

An administrative proceeding will be always initiated by the SDE[90], after it carries out preliminary investigations and send it to the analysis of the CADE[91]. Once the SDE concludes its preliminary investigations, which shall be done in sixty days, it will determine either the initiation of administrative proceedings or will conclude that there is not enough evidence to characterise an infringement against the economic order[92].

If the preliminary investigations conclude for the initiation of administrative proceedings these shall start in eight days, counted from the date of the conclusion of the preliminary investigations. The violator will be invited to produce his arguments within fifteen days. This initial phase of the proceeding includes the assessment of proofs and documents and the hearing of witnesses. Once this phase is concluded, the case will be submitted for judgement before the CADE.

---

administrative processes; to initiate an administrative process; to submit for the consideration of the CADE decisions on the conclusion of preliminary investigations or on administrative proceedings; to carry on research and studies aiming at guiding national policies on the repression of acts against the economic order; and to inform the public about the various forms of violation of the economic order which are prohibited by law (Law 8884/94, Art. 14).

[89]Law 8884/94, Art. 7.

[90]*Ibid.*, Art. 14 (VI).

[91]*Ibid.*, Arts. 30. *Cf.* Art. 14 (III).

[92]*Ibid.*, Art. 31. In the case of concluding that there is no breach of the rules on competition law, the SDE shall submit such considerations to the CADE for final decision.

Once the proceedings are received by the CADE, it will collect all the documentation necessary, request legal advice from the its Legal Counselling Department[93] and will decide upon the case[94].

There is also provided a consultation mechanism in which anyone may submit a situation to the CADE, asking for their advice on whether such situation would be characterised as against the economic order or not. The consulting party shall produce all the documentation necessary to enable the assessment of the specific circumstance and the CADE will issue an opinion within sixty days. If the situation object of assessment is found against the economic order, the CADE is not allowed to impose sanctions or penalties upon the consulting party.[95]

Any act which is capable of being against the economic order must be submitted to the CADE. If the following conditions are met, such acts will not fall within the prohibitions determined by Law 8884/94: (a) that their object is to increase productivity, to raise the quality of the product or service in question or to stimulate technological and economic development; (b) that the benefits arising from the act in question are equally distributed among the consumers; (c) that such behaviour does not favour the elimination of competition in a substantial part of the relevant market; and (d) that limits are imposed to reach the proposed objectives[96]. Additionally, those acts necessary on grounds of national economic needs and common benefit, and that will not cause damage or loss to the consumer, will be allowed[97].

---

[93] *Cf.* Arts. 10 and 11.
[94] Law 8884/94, Arts. 42 to 51. The decisions of the CADE are not subject to any other administrative appeal (*Ibid.*, Art. 50).
[95] *Ibid.*, Art. 59.
[96] *Ibid.*, Art. 54 (1).
[97] *Ibid.*, Art. 54 (2).

2.3. The negotiations in the MERCOSUL

The setting up of common rules for the protection of competition within an integrated market, and the relation of the participants of this integrated area with the outside world, is an essential condition for the proper functioning and operation of a Common Market. These issues have been discussed in detail in the context of the European integration process. In the MERCOSUL, the Treaty of Asuncion did not provide such a detailed framework as the EC Treaty did, but a general rule was established.

The Treaty of Asuncion, in Article 4, states that "... States Parties shall ensure equitable trade terms in their relations with third countries". This will be done by using their domestic legislation "... to restrict imports whose prices are influenced by subsidies, dumping or any other unfair practice". Additionally, Article 4, Last sentence of the Treaty of Asuncion determines that "... States Parties shall coordinate their respective domestic policies with a view to drafting common rules for trade competition". The first part of Article 4 clearly suggests that States Parties are committed to use their existing legal mechanisms to restrain advantages given to foreign companies by their own governments when they will be competing with the products of the MERCOSUL. Last sentence of Article 4, on the other hand, determines that States Parties of the MERCOSUL will negotiate common rules on competition, aiming at harmonising the rules related with the competitive practices of undertakings from third countries. But States Parties shall also agree upon common rules to regulate the commercial practices of their own undertakings. Negotiations are in the process of deciding upon these common rules, though the present Sub-section

will deal only with the negotiations towards the MERCOSUL's common internal competition rules.

It is firstly important to mention that, as far as competition rules are concerned, Argentina and Brazil appear to be the most advanced countries in this field in the MERCOSUL. This is not only because they are the most competitive markets among the participating countries of the MERCOSUL, but also because they have, from the beginning of the century, established a legislative history in this field[98].

Current negotiations in the MERCOSUL are in the stage of considering a list of priority points of harmonisation for the protection of competition in the MERCOSUL[99], issued during the Ministerial Meeting at Ouro Preto, Brazil, in 1994. These listed points are the result of the negotiations that have been carried out at the Committee on the Protection of Competition, as part of Sub-group 10 of the Treaty of Asuncion and are considered the basis for common rules on competition.

The Annex of Decision 21/94 divide the issues into two major parts. Firstly it suggests norms for regulating agreements between undertakings, and, secondly, it proposes mechanisms for controlling the practices of undertakings which are in a dominant position in substantial part of the MERCOSUL or in the whole of its territory.

Point 3 of the Annex of Decision 21/94 suggests that agreements and concerted practices between undertakings, as well as associations of undertakings

---

[98]**José Matias Pereira**, Regimes the Concorrência e Políticas de Concorrência na América Latina: o Caso do MERCOSUL, [1995] 16 *BILA*, as downloaded from *http://www.mre.gov.br/getec/webgetec/bila/16/4notas/4nota.htm*, states that the first legislation aiming at the protection against unfair competition in Latin America emerged in Argentina (1919), Mexico (1934), Brazil (1938), and Chile (1959).

[99]Included in the Annex of Decision MERCOSUL/CMC/N. 21, of 15 December 1994. Hereinafter referred to as "Decision 21/94".

aiming at, or with the effect of, impeding, restricting or distorting competition, will be prohibited[100]. Point 3 lists some practices, in the context of agreements or concerted practices, or associations between undertakings, that will be considered against unfair competition law, such as: fixing, directly or indirectly, buying or selling prices, as well as any other conditions for the production or commercialisation of products or services; limiting or controlling production, distribution, technological development or investments; dividing markets for products or services or dividing sources of supply of raw materials; co-ordinating actions which affect, or may affect, competition, contests, auctions or public bidding; adopting, in relation to other contracting parties, uneven conditions, putting the third contracting party in a condition of disadvantage in relation to other competitors; making the availability of commercial contracts, either oral or written contracts, linked to other matters which have no relation to the subject-matter of the contract in question; and putting pressure on clients or suppliers to act in a specified way.

With regard to dominant position of undertakings, Point 4 of the Annex of Decision 21/94 affirms that the abuse of a dominant position in part or in the whole of the MERCOSUL should be prohibited[101]. A non-exhaustive list of examples of abuse of a dominant position is given as follows: to impose, directly or indirectly, selling or buying prices or other conditions; to restrain, without justification, production, distribution or technological development, causing damage to other companies or to consumers; to apply better conditions to contracts having the same subject-matter to

[100]It is also considered by Point 3 of the Annex of Decision 21/94 that these acts are also prohibited when they have the object or effect of impeding, restricting or distorting the free access to the production, processing, distribution and commercialisation of products or services, in part or in the whole of the MERCOSUL, being able to affect the internal trade in the MERCOSUL.

different contracting parties; to refuse, without justification, the sale of goods or the provision of services; and to sell goods or services at prices below the usual price, or prices below the cost of production, aiming at eliminating competition in the market.

Co-operation among the States Parties will take place in order to assure that competition rules are applied in adequate forms throughout the MERCOSUL. This co-operation mechanism may be through the exchange of information, consultation, advice, technical co-operation or other mechanism[102]. The MERCOSUL Trade Commission will be empowered to apply the legal instruments for the protection against unfair competition[103].

CONCLUSION

Chapter 3, above, described the complex set of constitutional rules and secondary legislation designed by the European integration project to implement the principles of free movement of goods and competition law. As has been seen, the EC has established, already in its constitutional mechanism (the EC Treaty), detailed rules guiding the implementation of such principles. In contrast, the Treaty of Asuncion, as a constitutional pre-project of a Common Market, provided little, if any, guidance to the implementation of such principles, but recognised its importance for the establishment and operation of the envisaged Common Market.

The fact that the Treaty of Asuncion only recognises the importance of the establishment of those two principles, without providing further detail on how they

---

[101] The practices of all undertakings which have a participation above 20% of a relevant market will be controlled by the States Parties (Annex of Decisions 21/94, Point 5).
[102] Annex of Decision 21/94, Point 6.
[103] *Ibid.*, Point 8.

should be implemented, is not necessarily a fact which runs against the successful implementation of the integrating project of the MERCOSUL. It is necessary to remember that the Treaty of Asuncion is a regional agreement "for the establishment of a Common Market". As a consequence, the necessary legal and conceptual definitions of these principles should be determined as part of the process itself, while a final agreement in this regard should be built through the implementation of the Common Market as such.

In relation to the application of the free movement of goods principle a few remarks are necessary. In the first place, it is possible to affirm that the approach taken by the Treaty of Asuncion seems correct, for the purposes that it was designed. The Treaty of Asuncion only states that free movement of goods is one of the components of the Common Market that will be established between the States Parties of the MERCOSUL. However, as the Common Market goal is approaching, further interpretation of the application of this principle is necessary. Implementation of such general understanding seems vital in the very near future. Secondly, and particularly related to the application of the principle in connection with intellectual property protection, it is necessary to include clear guidelines on a common agreement on IPRs for the MERCOSUL. Such agreement should provide detailed understanding of the questions that may arise from the application of this principle *vis-a-vis* the exercise of IPRs. The legislative and juridical experience of the EC can be used as a very important example for the establishment of such rules. Chapter 3 has proved that, in practice, the implementation of the general principle that goods shall circulate without restrictions in the territory of a Common Market is not necessarily

an easy task. Several circumstances arise from the interpretation of the law and they must be established in a harmonised and coherent way.

With regards to the implementation of common competition rules, the MERCOSUL has already agreed upon advanced points of law which should be implemented in this context. It is probably possible to argue that the negotiations towards the regulation of anti-competitive practices in the MERCOSUL has reached a more comprehensive level of discussion than other intellectual property-related matters. The discussion currently held in the context of the MERCOSUL will probably lead the States Parties to agree upon a detailed legal framework for the application of anti-competitive rules for the integrated area.

The harmonisation of legislation, in this regard, however, seems limited if there is no institutional mechanisms designed to apply the common rules in the whole territory of the MERCOSUL. As has been pointed out several times in the present research, the way that national authorities and national courts will deal with the subject is still a question left for the future. In relation to the enforcement and application of these common rules, particularly those described in this Chapter and directly related with common policy instruments, the MERCOSUL Trade Commission seems to be the appropriate administrative organ to impose the application of the common rules on the free movement of goods and competition law principles. The problem arises when disputes are brought to national courts. A non-harmonised approach towards the application of such principles will definitely take place, which emphasises the need of a common juridical mechanism to unify the interpretation of the common legislation of the MERCOSUL.

It may appear to reader that the discussion attempted throughout the present research, as within the limits determined by the general Introduction of the thesis, would be near to conclusion. However, it is this researcher's personal opinion that the discussion proposed would not be completed without the inclusion of another very important and modern aspect relating IPRs to technological development and liberalisation of trade. The issues on biodiversity protection and sustainable development, liberalisation of trade and IPRs are very much inter-connected. The following Chapter was included hence as a complementary discussion attempting to make these links clearer, by discussing the "Biodiversity Related Aspects of Intellectual Property Rights".

CHAPTER 7
BIODIVERSITY-RELATED ASPECTS OF IPRs

INTRODUCTION

The present research analysed in the foregoing Chapters what may be called the "traditional" debate about patent protection. This discussion is broad and includes several other issues that are similarly important. Above, emphasis was given to the commercial aspects of the exercise of patent rights within an integrated area, such as the free movement of goods and anti-competitive law principles (discussed in Chapters 3 and 6, *supra*), and the substantive aspects of patent protection, such as pharmaceuticals, biotechnology and plant varieties (discussed in Chapters 4 and 5, *supra*). Unavoidably, some discussion about institutional aspects related to patent rights has taken place, particularly referring to the European integration project (Chapter 4) and to the international negotiations on patent protection (Chapter 2).

Within the context of the MERCOSUL, particular attention will be given to the modern discussion about the protection of the environment and its relationship with IPRs. The territory of the MERCOSUL is rich in natural resources and the commercial or scientific exploitation of these resources may give rise to other legal consequences in the context of an integrating project. There is a need to determine how the integrated area of the MERCOSUL will deal with these modern aspects of IPRs and how to envisage a framework of regional science and technology and environmental policies. The establishment of common policies on access to genetic resources and biodiversity conservation must be viewed in regional terms, as an attempt to develop strategies and mechanisms for technology transfer from technologically-developed countries or regions.

This Chapter must be viewed as a complementary resource to guide the regional implementation of multilateral principles for biodiversity protection and sustainable use, by providing an overview of the legal discussion in the international level and in Brazil.

1. THE SETTING UP OF NEW INTERNATIONAL REGULATIONS

In the last decade, the debate on the protection of the environment has grown impressively. The progressive misuse of the environment has led to the destruction of natural resources, consequently threatening the "biological diversity"[1] that still remains in the world. Further, considering the industrial progress and the "needs" of modern society, dangerous consequences have been noticed in the climate and atmospheric conditions of the planet. As noted by Bergel, industrialised nations - on grounds of unlimited progress and free market principles - have been disrupting the balance between ecological systems. In fact, "the dominant paradigm of development is contrary to the inter-relationship between the various natural processes and the argument that human life is placed in an environment which does not exist to be destroyed"[2].

Within the UN system, concerns on environmental protection have been present since the early 1960s as a result of technical studies carried out by some UN organisations or specialised agencies in their specific field of activities. The growing

---

[1] See note 17, *infra*, for the definition of biological diversity.

[2] **Salvador Dario Bergel**, Desarrollo Sustentable y Medio Ambiente: La Perspectiva Latinoamericana, [1992] 41 *Revista del Derecho Industrial* 303-343, at 303. See, also, **Jorge A. Kors**, Nuevas Tecnologías y Derecho Ambiental, [1992] 41 *Revista del Derecho Industrial* 389-419, at 397, where he affirmed that there is a need to include an ecological dimension in the debate on

importance of this issue, however, was formally recognised by the UN during the United Nations Conference on the Human Environment (UNCHE)[3], held at Stockholm from 5 to 16 June 1972.[4]

The UNCHE resulted in an Action Plan for the Human Environment[5], which rearranged all the recommendations approved by the conference, and a Declaration on the Human Environment[6], comprised of twenty six principles. Within this framework general principles were established, providing a basis for the necessary measures to protect the human environment and for an institutional framework to co-ordinate actions on environmental protection.

A Resolution on Institutional and Financial Arrangements[7] suggested the establishment of a programme, under UN auspices, to co-ordinate all environmental activities on national and international levels, to monitor the environment, to support environmental education programmes, and to attempt to create international laws, as well as to develop environmental guidelines and model laws to be used in the implementation of the Action Plan for the Human Environment. As a consequence, the United Nations Environment Programme (UNEP) was formally created by General Assembly Resolution 2997 (XXVII) of 15 December 1972[8].

---

industrial and technological development, aiming at maximising the quality of the environment when related to the negative repercussion of economic expansion.

[3]This conference was convened by General Assembly Resolution 2398 (XXIII) of 3 December 1968 (**Rüdiger Wolfrum & Christiane Philipp**, United Nations: Laws, Policies and Practice, London: Martinus Nijhoff Publishers (1995) V. 1, p. 488).

[4]A comprehensive chronological list of international arrangements in the field of environmental protection is available in **Edith Brown Weiss** (ed.), Environmental Change and International Law, Tokyo: United Nations University Press (1992), Appendix B, pp. 479-490.

[5]Published in 11 *ILM* 1421 (1972).

[6]Published in 11 *ILM* 1416 (1972).

[7]Published in 11 *ILM* 1466 (1972).

[8]UNEP is an integrated programme, not a specialised agency of the UN, although it enjoys a reasonable level of autonomy. It is comprised of the following bodies: the Governing Council, the

Twenty years after the Stockholm conference, the United Nations Conference on Environment and Development (UNCED) was held from 3 to 14 June 1992 in Rio de Janeiro, Brazil. The UNCED approved the following instruments: the Rio Declaration on Environment and Development (the Rio Declaration)[9]; the Agenda 21[10]; a Statement of Principles for a Global Consensus on the Management, Conservation and Sustainable Development of all Types of Forests[11]; the Framework Convention on Climate Change[12]; and the Convention on Biological Diversity (CBD)[13].[14]

Although other non-legally binding instruments which have arisen from the UNCED[15] contain principles and plans of actions relating with the conservation and the sustainable use[16] of biological diversity[17], the CBD will be used as a main reference in this Chapter.

Environment Secretariat, the Environment Co-ordination Board, and the Environment fund. See, for further information about the UNEP, **Rüdiger Wolfrum & Christiane Philipp**, United Nations: Laws, Policies and Practice, London: Martinus Nijhoff Publishers (1995), V. 2, pp. 1296-1304.

[9]Published in 31 *ILM* 874 (1992).

[10]Published in Earth Summit 1992, London: The Regency Press Corporation (1992).

[11]Published in 31 *ILM* 881 (1992).

[12]Published in 31 *ILM* 849 (1992).

[13]Published in 31 *ILM* 818 (1992). The CBD has entered into force on 29 December 1993 (in *http://www.unep.ch/biodiv.html*) and, on 8 March 1996, has been ratified by 144 countries (in *http://www.unep.ch/bio/ratifica.html*).

[14]The full text of all the documents above-mentioned are also available in the Internet as follows: *gopher://infoserver.ciesin.org./11/human/domains/political-policy/intl/confs/UNCED/unced-finals*.

[15]Particularly the Rio Declaration and the Agenda 21.

[16]Article 2 of the CBD defines "sustainable use", for the purpose of the application of the Convention, as "... the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generation".

[17]Article 2 of the CBD defines biological diversity (or biodiversity) as "... the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems". Although the CBD did not attempt to define species within this context, it has provided a definition, also in Article 2, of "biological resources": "... includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity".

The biological diversity of the planet is regarded as one of the most significant sources of products that may be developed in the future by multinational companies in the pharmaceutical and/or biotechnology fields[18]. Both economic sectors are planning their future based on the exploitation of the unknown resources that the world's biodiversity may provide. A high percentage of the products developed today in these areas come from the raw materials contained in the forests of developing countries. The CBD's approach to the use and exploitation of biological material is seen by the private sector as a critical threat to future plans. The uncontrolled use of these resources will be a significant threat to the environment and to the biological diversity that remains for present and future generations. These key economic sectors have, therefore, seen the environmental crisis, and the legal response thereto in the CBD, as a mechanism which might threaten future research into new products that use, as a primary basis, genetic resources[19] which are found mostly in the territories of developing countries.

The use and exploitation of biological resources is undoubtedly one of the most controversial issues in the international debate. For example, during the signing of the Convention on Biological Diversity in 1992, the United States refused to accept

---

[18]**Darrell Posey**, Intellectual Property Rights and Just Compensation for Indigenous Knowledge, [1990] 4 *Anthropology Today* 13-16, at p. 15, estimates that the annual market for medicines derived from medicinal plants discovered from indigenous peoples is of 43 billion US dollars. Further, he reckons that "... less than 0,001% of profits from drugs that originated from traditional medicine have ever gone to the indigenous peoples who led researchers to them". See, for further estimates, **Stephen Brush**, Indigenous Knowledge of Biological Resources and Intellectual Property Rights: the Role of Anthropology, [1993] *American Anthropologist* 653-686, and UNEP Doc. N. UNEP/Bio.Div./Panels/Inf.2 (28 April 1993) Expert Panels Established to Follow-Up on the Convention on Biological Diversity - Report of Panel II: Evaluation of Potential Economic Implications of Conservation and Its Sustainable Use and Evaluation of Biological and Genetic Resources.

"... the text's treatment of intellectual property rights ... technology transfer and biotechnology"[20]. Further, the Commission of the European Communities has expressed its concerns in relation to the interpretation given to some articles of the Convention, in particular Articles 15 (access to genetic resources), 16 (access to and transfer of technology), 19 (handling of biotechnology and distribution of its benefits) and 22 (relationship with other international conventions)[21]. It is possible to assume that - taking into account the reaction of the most important trading nations - when industrialised countries became concerned with the protection of the environment, their main interest was far from the protection of the environment itself. Economic and commercial interests have probably been of more importance, when included in this discussion, rather than the need to save the planet's biological diversity.

As highlighted by Lesser[22], "IPRs and biodiversity are conceptually unrelated, at least at the primary and secondary levels .... Where they are associated is through the Biodiversity Convention, and there in the public mind largely because then-US President Bush opposed signing in response to an interpretation unfavourable to IPRs".[23] Later, Lesser notices that the issues raised by the US focus primarily on modern biotechnology and, where the CBD establishes the right of national governments to control the access to genetic resources, in Article 15, it

---

[19]The CBD, in Article 2, defines "genetic resources" as "... any genetic material of actual or potential value", whether "'genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity".

[20]Declaration of the United States of America, as in 31 *ILM* 848 (1992).

[21]**Commission of the European Communities**, Draft Interpretative Declaration (on the occasion of the ratification of the Convention on Biological Diversity, (16 April 1993).

[22]**W. Lesser**, Institutional Mechanisms Supporting Trade in Genetic Materials: Issues under the Biodiversity Convention and GATT/TRIPS, Geneva: UNEP (1994), p. 22.

[23]The US eventually signed the CBD, under Clinton's administration, on 4 June 1993. See, for this information, **Joseph Straus**, The Rio Biodiversity Convention and Intellectual Property, [1993] 5 *IIC* 602-615, p. 608, para. 12.

> does not specifically refer to IPRs as is done in Article 16 (3). The connection may, however, be made by noting that IPRs would provide a possible mechanism for controlling the movement and use of genetic resources as authorised by this Article.[24]

Concerns about environmental protection have raised several issues in connection with the exploitation of biodiversity, consequently changing the ecological and economic importance of the subject. The traditional concept of IPRs has been broadened substantially in accordance with the development of new technologies and the needs of modern society.[25] After the commitments achieved by the UNCED, namely the CBD, other aspects of intellectual property protection were raised.

The CBD's main objectives are three-fold: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. These goals are to be achieved by appropriate access to genetic resources and by appropriate transfer of relevant technologies, which has given rise to the methodological division that follows in the present Chapter. Access to genetic resources and access to and transfer of technology are however all inter-connected issues.[26]

---

[24]**W. Lesser**, note 22, *supra*, p. 23.

[25]See, generally, Chapter 2, *supra*, for further analysis of the international debate on intellectual property protection.

[26]The objectives of the CBD, as well as the mechanisms described for attaining such objectives, are listed in Article 1.

2. ACCESS TO GENETIC RESOURCES AND RELATED ISSUES

For millennia genetic resources were regarded as "the common heritage of mankind"[27]. Although the CBD is the first legally-binding international instrument to admit that States have sovereign rights over their own genetic resources, the discussion on national jurisdiction to biological resources is not really a very contemporary one. UN General Assembly Resolution 1803 (XVII) of 1962[28] declared, for the first time, the permanent sovereignty of States over their natural wealth and resources and that national jurisdiction and legislation should apply for the control and the exploitation of these resources.

The Declaration on the Human Environment of 1972 also affirms, in Principle 21, that States have sovereign rights to exploit their own resources based on their own environmental policies. States are additionally liable to ensure that activities under their jurisdiction or control do not cause damage to areas beyond the limits of their national jurisdiction[29].

The provisions which have arisen from the text of the CBD have brought these issues on to a much more complex level of discussion, linking economic activities with sustainable use of natural resources by accepting the market value of the latter[30]. But

---

[27]The expression "common heritage of mankind" has emerged from the UN's efforts to codify international law of the sea and of the outer space in the late 1960s. The concept includes the idea that some territories (such as the Antarctica) and some resources are of importance to all, and that "... they should be preserved in the common interest of all states, or explored and used in a way that allows all states to participate and enjoy their benefits" (**Rüdiger Wolfrum & Christiane Philipp**, note 3, *supra*, p. 149).

[28]*Apud* **Ian Brownlie** (ed.), Basic Documents in International Law, Oxford: Clarendon Press (1983), 3rd ed., pp. 231-234.

[29]Article 3 of the CBD literally repeats Principle 21 of the Declaration on Human Environment.

[30]This link is made clear by the reading of the Preamble of the CBD which initially recognises "... the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific,

the acceptance that genetic resources are within national jurisdiction does not appear to be exhaustive. There are several other concerns related to the conservation and sustainable use of these resources which were expressed by the CBD in connection with the exploitation of biological diversity.

The CBD recognises that genetic resources are within the sovereign rights of national States, which will have the authority to create legal mechanisms to control the use of these resources. The CBD, further to the application of this principle, affirms that access to genetic resources shall be facilitated, but such access should be with the prior informed consent of the country providing the genetic resources, which will also be entitled to a equitable and fair share of the benefits that may arise from the commercialisation of the resources. The country which provides the genetic resources shall also be entitled to participate in the scientific researches based on the genetic resources in question.

2.1. A brief assessment of the application of the sovereign rights principle

The CBD, in Article 15 (1), recognises that States have sovereign rights over their natural resources and that "... the authority to determine access to genetic resources rests with national governments and is subject to national legislation"[31]. There are several considerations which arise from the wording of Article 15 (1), CBD, which

---

educational, cultural, recreational and aesthetic values of biological diversity and its components". Further, while the CBD recognises States' sovereign rights over their biological resources it affirms that States are also "...responsible for conserving their biological diversity and for using their biological resources in a sustainable manner".

[31] *Cf.* Principle 2 of the Rio Declaration.

are to be taken into account in the context of the implementation of the general principle.

It is not clear, in the light of Article 15 (1), CBD, whether the concept of sovereign rights precludes or reaffirms the concept of proprietorship in connection with access to genetic resources. In order to assess this apparent ambiguity, it is necessary to examine the wording of Article 15 (1), CBD, in more detail.

The concept of sovereignty emerged in the Middle Age from the notion that the sovereign had supreme power over his territory. This was regarded as necessary at that time to secure the power of a sovereign constantly threatened by civil war and by conflict with the Catholic Church. This concept has led to the notion of sovereign States, which has been interpreted in several ways through the centuries.[32]

Today, the concept of sovereignty of States is closely dependent upon the international legal order made applicable by the principles of international public law. Sovereign rights thus mean that a State is recognised by the international community as such, having legal personality, and that "[t]he legal competence of states and the rules for their protection depend on and assume the existence of a stable, physically delimited, homeland"[33]. It seems clear that the concept of sovereignty is mainly applicable to a specific territory where a particular State has exclusive jurisdiction[34].

---

[32]See, *e.g.*, **Celso D. de Albuquerque Mello**, Direito Internacional Econômico, Rio de Janeiro: Renovar (1993), p. 46, and **Malcom N. Shaw**, International Law, Cambridge/United Kingdom: Grotius Publications Limited (1991), 3rd ed., p. 25.

[33]**Ian Brownlie**, Principles of Public International Law, Oxford: Oxford University Press (1990), 4th ed., p. 108.

[34]As described by **Malcom N. Shaw**, note 32, *supra*, at p. 393, "[j]urisdiction concerns the power of the state to affect people, property and circumstances and reflects the basic principles of state sovereignty, equality of states and non-interference in domestic affairs. Jurisdiction is vital and indeed central feature of state sovereignty, for it is an exercise of authority which may alter or create or terminate legal relationships and obligations".

Sovereign States are, therefore, responsible, under their own institutional/governmental framework, to rule upon the lives of their citizens and their public or private undertakings, to determine their legal obligations and the legal framework, and to exercise this power against the threat of other nations to their territory.

On the other hand, the concept of ownership, in this connection, seems to be closely related to the concept of sovereignty. The State is the proprietor of its territory establishing, through its constitutional framework, what is to be considered therein. Territorial sovereignty does not preclude the ownership, but merely reaffirms it[35].

Having said that, one must understand that the wording of the CBD, after giving emphasis to the sovereign rights concept in relation to access to genetic resources in the Preamble and Article 3, points out that States, in addition to the recognition of sovereign rights over their own natural resources, have the authority to determine by national law how these resources are to be exploited, in Article 15 (1).

It seems that the discussion of sovereignty in this context is vital for the debate and of paramount importance for developing countries which possess much of the biological diversity of the planet. If one begins to challenge the concept of sovereignty, as precluding ownership[36], this will involve a major change in the international legal framework by putting aside the development of the sovereign rights

---

[35]Opposing to this argument, **Lyle Glowka, Françoise Burhenne-Guilmin & Hugh Synge** (in collaboration with Jeffrey A. McNeely and Lothar Gündling), A Guide to the Convention on Biological Diversity, Gland/Switzerland and Cambridge/United Kingdom: IUCN (1994), p. 76, says that "... questions of ownership are not addressed by the text of the Convention, but are determined by national law".

[36]As **Lyle Glowka** *et al.*, note 35, *supra*, has done.

principle despite its well established historical and legal framework. Although it is possible to argue that the concept of sovereignty does not necessarily assume the State's ownership over genetic resources, this is not the question at this specific moment. Constitutional laws, indeed, may play a determinant part in this context by affirming the proprietorship of natural resources within national territory, but, as a matter of fact, the CBD in no way avoids the concept of States' proprietorship over genetic resources.

The CBD suggests mechanisms that will have to be considered by both developed and developing nations' legal practice when utilising genetic resources for scientific or commercial purposes. As a consequence, national law will have to provide detailed mechanisms to implement the principle of sovereign rights over genetic resources so that this could apply in practice. A more detailed analysis of measures to be considered by national law will be provided below.

2.2. Mutually agreed terms and the requirement of prior informed consent

Based on the application of the principle of sovereign rights, the CBD has also established that access to genetic resources shall be on mutually agreed terms and subject to "prior informed consent" (PIC)[37]. These are different, but complementary, measures which will be determined by national legislation in this field.

The expression "mutually agreed terms" as used by the CBD is not defined in the Convention but seems to imply the existence of two parties in a contractual relationship: the provider of genetic resources and the potential user of it. This

relationship will be constructed by the consent of both parties and mutually agreed. The provider of genetic resources, the State, will have to define upon what terms this will apply, in combination with other aspects such as participation in research and development and the equitable and fair sharing of the benefits arising from the utilisation of genetic resources[38]. Glowka[39] understands that access agreements may become the most relevant mechanism to authorise parties to exploit genetic resources and to agree upon the terms of such exploitation. Therefore, either existing national contractual regulations or a more detailed form of legal mechanism will be created to provide the means of access agreements. A combination between the existing system regulating contract law and the system regulating access agreements is also foreseeable.

Some have suggested, for instance, "Material Transfer Agreements" (MTAs) as a mechanism that could possibly be used for regulating the relationship between the provider and the user seeking access to genetic resources. This type of agreement is commonly used by biotechnology industries and the academic community to facilitate the sharing of biological material aiming at mutual gain. At least two types of MTAs could be used for the purpose of accessing genetic resources: research-based and commercially-based agreements.[40]

---

[37]CBD, Arts. 15 (4) and (5), respectively.
[38]Discussed further in Sub-section 2.3, *infra*.
[39]Note 35, *supra*, p. 80.
[40]MTAs, as a possible contractual tool for regulating access to genetic resources, are suggested by some authors and by the Conference of the Parties of the CBD. See, *e.g.*, **Walter Reid**, Biotechnology, Technological Change, and Regulation of Access to Genetic Resources, paper presented at the Global Biodiversity Forum '95, Jakarta, Indonesia, 4-5 November 1995, pp. 17-20; **Daniel Putterman**, Model Material Transfer Agreements for Equitable Biodiversity Prospecting, *mimeo* (1995); and UNEP Doc. N. UNEP/CBD/COP/2/13 (6 October 1995) Access to Genetic Resources and Benefit-Sharing: Legislation, Administrative and Policy Information, pp. 25-26.

It is possible to argue that such a contractual relationship, either through MTAs or through other mechanisms, between the provider and the user of genetic resources will contain at least the following clauses: (a) the type of genetic resources for which access is to be authorised and for what purpose (commercial or scientific/academic) it is granted; (b) in which geographical area, if any, such resources are allowed to be exploited; (c) research participation; (d) technology transfer and ownership (IPRs) of the results of research; (e) royalty fees for accessing genetic resources; (f) limits on third party transfer; (g) measures regulating the handling, transport, export and release of products arising from the research on genetic resources; (h) the duration of the access; and (i) dispute settlement.

The CBD additionally states that "[a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by the Party"[41].

Although the concept of PIC is present only in one other international instrument[42], it seems to be an important mechanism for the sustainable use of genetic resources. The idea of the introduction of the mechanism of PIC is closely related to the discretion of national legislation to regulate access to genetic resources. Although the CBD leaves discretion to the provider countries to decide whether to require prior informed consent or not, this seems to run counter to the objectives of the CBD itself. If there is no control for accessing genetic resources, or no prior consent authorising such access, the exploitation of genetic resources could be carried out without any

---

[41]CBD, Art. 15 (5).

[42]The Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposals, done at Basel in 1989 (**Lyle Glowka** *et al.*, note 35, *supra*, p. 80).

further regulation, possibly causing damage to the environment, destroying genetic resources and, of course, being against the sustainable use of biological diversity. In my opinion, it is unlikely that national legislation will fail to include provisions on PIC when discussing access to genetic resources.

PIC will probably take place through a written certificate granting the third party in question an authorisation to exploit and use genetic resources under the terms and conditions of the agreement which has been agreed mutually before consent is granted. A government authority will probably have to be created (or an existing one will have to be empowered) to grant such certificates, and will have the additional tasks of analysing the conditions previously established by the agreement in question and of controlling compliance by the third party to the terms of the access agreement. Such a certificate will be probably based on the terms and conditions created by the agreement, and will be enforced by national laws of the country providing genetic resources. Probably, when establishing administrative mechanisms for granting or refusing access to genetic resources, national laws will also provide for some kind of administrative appeal against decisions denying access to genetic resources, and for penalties and sanctions for non-compliance with the terms of the access agreement or non-fulfilment of the requirement of having a written form of PIC before exploitation of genetic resources occurs.

Lastly, it is important to mention that for all that has been said above to take place, it is necessary that the country providing genetic resources has the capacity to analyse and negotiate all the information provided by the third party wishing to have access to genetic resources, as well as technical ability to assess whether or not such

access will take place in an environmentally sound manner[43]. This technological capability may not be present in most of the countries which are providers of genetic resources, but can be built through technology transfer arrangements and through international co-operation among developing countries themselves. It also seems to be the task of the Conference of the Parties of the CBD to find mechanisms to be used in building up such capabilities.

2.3. Scientific research on genetic resources

As has been mentioned in the foregoing Sub-section, the CBD attempts to regulate the situation between the country providing genetic resources and the user. Genetic resources are recognised today as the main source of products for research in the pharmaceutical, biotechnological, and agricultural fields.

There are at least two types of research which will use genetic resources as a main basis and which shall be regulated by national legislation by virtue of Article 15 of the CBD. The country providing this genetic material will have to consider, firstly, if the resources in question will be used only for academic and research purposes, only for commercial purposes, or for both. This difference leads to distinct approaches which must be considered by national legislation and by access agreements.

The CBD requires that there be equitable sharing of the benefits of the use of genetic resources on a financial, scientific and technological basis. The sharing of these benefits shall moreover be in compliance with the other two objectives of the

---

[43] **John Mugabe**, Governing Access to Genetic Resources: Emerging National Policy, Legal and Administrative Regimes, paper presented at the Global Biodiversity Forum '95, Jakarta, Indonesia, 4-5 November 1995, p. 3.

CBD, *i.e.* the conservation of biological diversity and the sustainable use of its components[44]. The sharing of the benefits is to be considered taking into account both how genetic resources are going to be used, if commercially or only for scientific purposes, and what type of benefits will be shared (financial, scientific or technological).

When countries providing genetic resources negotiate the supply of genetic resources to third parties, they will have to consider their participation in the scientific research that will be carried out, the sharing of the benefits arising from this research, and whether or not this research, or the result of it, may cause risk or damage to the environment or to human, plant or animal health.

2.3.1. The full participation of the provider

The CBD considers the level of technological development of developing countries which are the providers of genetic resources and suggests that scientific research based on genetic resources provided by a specific country should be with the participation of such country and should take place in the provider country.[45] These provisions aim at encouraging appropriate transfer of technology and building the capacity of developing countries.

The wording of Article 15 (6), CBD, is general and not obligatory. The provision says that participation shall be encouraged in this manner. Although this seems to be addressed directly to developed nations' governmental agencies and

---

[44]CBD, Art. 1.

[45]CBD, Art. 15 (6). Similarly, the CBD suggest the participation of the country provider in scientific research based on genetic resources, in Articles 18 and 19 (1).

private research companies, the letter of Article 15 (6), CBD, also appears to suggest that such mechanism should be encouraged by national legislation of the country providing the genetic resources and by access agreements.

These measures must be defined by national legislation and determined by the access agreements. The cost of participation in scientific research and the material for building capacity for provider countries shall be considered. Generally speaking, countries and/or undertakings utilising genetic resources for scientific research shall bear the costs of the participation of the country providing these resources.

In relation to the aspects of IPRs arising from research based on genetic resources, there are other important considerations. This seems to be a matter to be decided by the negotiations on the access agreements. Usually the participating country, as a contributor to the scientific research, should also be able to share the "ownership" of the IPRs which are a possible outcome of the scientific research in question. However, provider countries may consider giving up the IPRs of the outcome of scientific research if the user company or country invests considerable amounts in the transfer of relevant technology and on the human resources and capacity building of the country providing the genetic resources. A balance shall be permitted by national legislation and shall be considered in the setting up of national science and technology and industrial policies.

The issues about IPRs will also have to be considered in the context of the agreement itself. If the agreement is merely for scientific research with no commercial aim, it seems that the issues of IPRs could not be relevant if this scientific aim is explicitly referred to in the access agreement and no commercial end is envisaged. On

the other hand, if the access agreement has the objective of directly or indirectly developing a product which will be commercialised, the issues of IPRs will have to be taken into account in more detail.

2.3.2. Fair and equitable share of the benefits

Article 15 (7), CBD, obliges Contracting Parties to take legislative, administrative or policy measures to share "... in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources". This shall be done on mutually agreed terms[46].

It is firstly necessary to mention that the wording of Article 15 (7), CBD, is addressed to both developed and developing nations, implying a two-way relationship. These measures (legislative, administrative or policy) will have to be complemented by each other's understanding of the results of research and development of genetic resources, and the research or commercial value of the genetic resources provided will have to be considered in a case-by-case basis.

Article 15 (7), CBD, makes a clear distinction between two benefits that may arise from scientific research based on genetic resources: scientific benefits, or research and development results; and the commercial or other benefits as an outcome of the research based on the genetic resources provided.

It is difficult to predict all types of benefit that might arise from the use of genetic resources, either as a result of pure scientific research or by the further

---

[46] *Cf.* Sub-section 2.2, *supra*.

commercialisation of these results, and how these benefits should be shared. Thus, national legislation will have to be flexible in considering the wide range of benefits that may be shared.

In relation to the sharing of scientific benefits, for instance, there are a few questions to be considered. One should bear in mind that the results of research and development may lead to the creation of products and/or technologies which may be deemed strategic for both parties, the country providing the genetic resources and the user who access has been granted to. In this situation, the sharing of the benefits may be based on technology transfer and support of the development of human resources. The provider country may, for instance, request the user of genetic resources to bear the costs of the participation of scientists in the research and development activities based on the genetic resources in question. The provider country may also request that the research and development activities take place in its territory and that the equipment and all infra-structure necessary to carry on the research be left in the country provider.

The user of genetic resources may also suggest some conditions for sharing the benefit of the results of scientific research. He may, for instance, request to be the holder of the appropriate IPRs on the results of the research, and to be in a more favourable position to have access to other genetic resources in the provider country. He may also wish to have exclusive rights over those genetic resources for a specific period of time.

In considering the sharing of benefits arising from the commercial use of genetic resources, other aspects must be analysed. It is firstly necessary to mention

that, when commercial activities are linked with research based on genetic resources, monetary benefits will play the most determinant part. Monetary benefits will take several forms in practice. The country providing the genetic resources may require advance payment for collecting genetic resources, payments for samples collected, minimum royalty fees for the future development of commercially valuable products, or a combination of all these. National legislation will also have to provide for mechanisms which recognise the value of indigenous and local knowledge in research on genetic resources. All these monetary benefits may be used as an additional fund to promote the sustainable use of genetic resources and, therefore, to protect biological diversity.

It is also important to note that Article 15 (7), CBD, makes reference to Articles 16 and 19 of the Convention. The main purpose of this cross-reference is to provide further support for technology transfer from the developed to the developing world (Article 16), and to expand the participation of the country providing the genetic resources in biotechnological research and in the benefits arising from biotechnological research which makes use of genetic resources (Article 19)[47]. It also has the objective of enhancing the appropriate and effective protection of IPRs related to research on genetic resources (Article 16).

Article 15 (7) also refers to Articles 20 and 21 of the CBD, which deals with the financial mechanisms to support biodiversity conservation. It is possible that the Convention aims at suggesting that "... the agreed full incremental cost of sharing research and development results and other benefits could be financed through the

---

[47] **Lyle Glowka** *et al.*, note 35, p. 82.

Convention's financial mechanism, if the Conference of the Parties decides that such activities are potentially eligible for funding (...)"[48].

2.3.3. Measures to regulate biosafety

Research based on genetic resources is likely to have as a final result products which are modified somehow by either traditional or modern biotechnology[49]. The modifications of the structure of living matters may have adverse effects on the environment and human, plant or animal health. It seems that, by its nature, modern biotechnology which genetically modifies living organisms by transferring genes between species, genera, and phyla, may be more likely to have adverse effects when deliberately released. This is also enhanced by the limited knowledge that modern science has on the future effects that products resulting from biotechnological research may have on the environment, human, plant or animal health.

As the CBD is designed to protect biodiversity by several means, including the use of biotechnological research techniques based on genetic resources, the issue of "biosafety"[50] is present, directly or indirectly, in several provisions. By virtue of

---

[48]*Ibid.*, p. 83. The "financial mechanism" of the CBD is provided by Article 21 and supplemented by Article 20. Article 21, CBD, calls for the establishment of a mechanism funded by the Contracting Parties (particularly developed countries) to provide financial resources to developing countries under the framework of the Conference of the Parties of the CBD. Such mechanism should also consider the existing financial mechanisms to provide financial resources for the conservation and sustainable use of biological diversity. In addition, Article 20 determines a commitment for all Contracting Parties to the CBD to fund the protection of biological diversity, also calling for additional funds from developed nations. It also takes full account of the specific needs of least developed countries in relation to funding and technology transfer.

[49]*Cf.* Chapter 5, Part 2, Section 2, *infra*.

[50]Since the first studies on infections acquired within the laboratories where biological research was conducted, in the 1960s, the definition of "biosafety" was developed. The 1960s saw a great advance in biotechnological research enhanced by the development of new technologies in genetic engineering methods. In the mid-1970s the World Health Organization (WHO) published a manual on biosafety in which this concept was widened by the inclusion of questions related with the

Articles 8 (g) and 19 (3) and (4), the CBD directly addresses the subject on two levels: national and multilateral. In several other provisions, the CBD addresses the subject of biosafety mechanisms indirectly or as a means of implementing the main goal of conserving and using genetic resources in a sustainable way[51]. This Paragraph analyses only the provisions which address the issues on biosafety in a direct sense.

Article 8 (g) of the CBD calls for the establishment of regulations to "... control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health". The CBD by the wording of this provision has attempted to broaden the traditionally applied concept of "genetically modified organisms" (GMOs) by using the term "living modified organisms" (LMOs). During the negotiations of the CBD, it seems that the prevailing notion was that the risks of release of GMOs were present more widely in the context of biodiversity conservation and that, in some circumstances, traditionally developed or bred

---

prevention of risks of various type, including physical, radioactive, chemical and biological risks. Developed countries, in particular European countries, started to issue regulations on the control of biosafety and, developing countries such as Brazil, with less biotechnological research capacity, regulated this issue for the first time in 1995 (**Carlos Médici Morel**, Biossegurança: Uma Nova Ciência?, *Anais da 47a. Reunião Anual da Sociedade Brasileira para o Progresso da Ciência*, V. 1 (July 1995), pp. 25-26). For further information on the existing instruments or guidelines dealing with biosafety measures see UNEP Doc. N. UNEP/Bio.Div./Panels/Inf.4 (28 April 1993) Expert Panels Established to Follow-Up on the Convention on Biological Diversity - Report of Panel IV: Consideration of the Need for and Modalities of a Protocol Setting Out Appropriate Procedures Including, in Particular, Advance Informed Agreement in the Field of the Safe Transfer, Handling and Use of Any Living Modified Organism Resulting from Biotechnology that may Have Adverse Effect on the Conservation and Sustainable Use of Biological Diversity, Annex II.

[51] *Ibid.*, UNEP Doc. N. UNEP/Bio.Div./Panels/Inf.4, states that it was agreed that other provisions of the CBD were also relevant to the discussion on the modalities and needs of a protocol on biosafety, such as Articles 6 (b); 7 (c); 8 (h); 14 (1)(a), (c) and (d); 17 (1); and 18 (3).

organisms could also pose risks to the environment and to the sustainable use of biodiversity[52].

The rationale of the obligation imposed by Article 8 (g), CBD, seems to be directly linked with national mechanisms for the control of the release of biotechnological research results, which should take place in a precautionary manner, based on the assessment of the risks and the subsequent management of the release of these products. It is, however, important to bear in mind that this obligation is addressed only to sovereign countries which are allowed to extend the application of such regulatory measures based on their own national legal framework. The CBD has, thus, approached the subject firstly on the national level to recognise, further, the need of a multilateral mechanism to control the release and handling of products that are the result of biotechnological research.

In Article 19 (3), therefore, the CBD has claimed that Contracting Parties should consider the need of a protocol to the Convention "... setting out appropriate procedures, including, in particular, advanced informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity". By analysing the wording of Article 19 (3), CBD, one should consider firstly that the negotiators accepted the need of domestic measures, in the light of Article 8 (g), CBD, but recognised that national law would be aided by the establishment of international standards in this regard. The CBD has also, by suggesting an assessment of the need for a protocol, accepted that the control of the

---

[52]**Lyle Glowka** *et al.*, note 35, *supra*, p. 45.

release and handling of LMOs is necessarily a matter of concern to all, and the recognition of measures to regulate such actions should have a multilateral approach in order to be effectively applied in a harmonised way world-wide. The release, without control, of a product resulting from biotechnological research in any area of the planet could have adverse effects on the biodiversity in any other place, which would run counter to the objectives of the CBD.

In this sense, one may argue that national measures in this matter could be undermined by the establishment of multilateral measures for biosafety. It appears that the objective of the negotiators was nevertheless in the opposite sense, that the CBD recognised the need of national measures which would be aided and in the future harmonised by the establishment of guidelines created by the protocol.

Article 19 (3), CBD, aiming at the conservation and sustainable use of biological diversity, has also included a term which shall be analysed further: "advanced informed agreement". It is possible that the negotiators of the CBD intended, with this expression, to create a set of procedures, incorporated in the principle that States have sovereign rights to control the transfer, handling and use of LMOs, including the right to refuse the importation of LMOs. Advanced informed agreement sounds similar to the mechanism of PIC discussed above in Sub-section 2.2. It is probably a mechanism which grants States rights to refuse the importation of LMOs which do not fulfill the requirements established by national legislation or, in this case, by the protocol on biosafety under the CBD[53].

---

[53]The importer of LMOs will probably have to provide basic information in relation to the organism that is intended to be imported into national territories, such as: the intended use, including the scale of use; the site for the intended use; information relating to the organisms, such as their common names, characteristics, where they are indigenous or commonly used; information on prior related

It is also important to note that the CBD does not necessarily claim that a protocol will be established. It merely calls for an assessment of the needs and modalities of such a protocol. In this way, the first meeting of the Conference of the Parties to the CBD, held in Nassau, Bahamas, from 28 November to 9 December 1994, established an "Open-ended Ad Hoc Group of Experts on Biosafety" (Biosafety Ad Hoc Group) with the mandate of considering the needs and modalities of such a protocol and assessing the existing knowledge, experience and legislation in this field. The Conference of the Parties to the CBD decided also to establish a panel of fifteen government-nominated experts to prepare a background document for the Biosafety Ad Hoc Group. The government-nominated experts group met in Cairo from 1 to 5 May 1995 and the Biosafety Ad Hoc Group met in Madrid, from 24 to 28 July 1995. The Biosafety Ad Hoc Group clearly concluded that there is a need for a protocol by virtue of Article 19 (3) of the CBD.[54]

It is also clear that the CBD, in addition to the call for an assessment of the needs of a biosafety protocol, further concluded that some bilateral-type of obligation on the import and export of LMOs was necessary. Article 19 (4), CBD, thus creates a bilateral obligation to provide information about LMOs before actual transfer of them takes place. Article 19 (4), CBD, establishes that "[e]ach Contracting Party shall, ...

---

releases: information concerning national risks assessments; information regarding the conditions of the release, for example, the quantity and time of release, the natural conditions of the geographical area where it is supposed to be released, and the characteristics of the flora, fauna and the environment that could be affected by such release; an analysis of the national socio-economic implications and impacts of the release; the type of transportation that will be used to transfer the organism, including the packaging and labelling characteristics; and information regarding the safe handling and use of the organisms (UNEP Doc. N. UNEP/Bio.Div./Panels/Inf.4, note 50, *supra*, Annex IV).

[54]See, generally, UNEP Doc. N. UNEP/CBD/COP/2/7 (3 August 1995), Report of the Open-ended Ad Hoc Group of Experts on Biosafety.

provide any available information about the use and safety regulations required by the Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced". This implies two types of obligation. The first obligation is the one which requires the exporting Contracting Party to provide information on the regulatory measures that it utilises for the safety handling of LMOs. In addition, exporting Contracting Parties could provide available guidelines and policies in this regard. This type of obligation is of a general character.

The second obligation is related to the supply of any information regarding possible adverse impacts of the LMOs which will be imported. The wording of Article 19 (4), CBD, *i.e.* "... any available information on the potential adverse impact ..." is very broad and seems to imply that the information in question could be concerned with adverse impact on biodiversity, as well as on human or animal health. In addition, this second obligation does not appear to require exporting Contracting Parties and private or public undertakings to generate information, but only to provide the information that is currently available[55].

Current negotiations on a protocol on biosafety lead one to think that such a protocol would contain at least the following provisions: (1) transfer of LMOs would take place after a minimum set of information is provided; (2) the supply of information must consider, primarily, the overall characteristics of the organisms, the potential receiving environment, and the interaction between these components; (3) regulation of biosafety should be based on a case-by-case and step-by-step approach,

---

[55]**Lyle Glowka** *et al.*, note 35, *supra*, pp. 98-99.

assessing whether or not there is enough experience and documentation available for the release of the organisms; (4) risk assessment and risk management should take place prior to the release of the LMOs; (5) assessment of the socio-economic impact of the release of organisms has to be provided; and (6) a clearing-house mechanism should be created to provide an effective link between national authorities, to support interaction among national authorities, to provide technical and scientific advice to national authorities, to establish relevant database on the release of LMOs, and to serve as the international body for overseeing the advanced informed agreement procedure.

Although that is not clear within the context of the negotiations of the CBD, a future biosafety protocol would need to contain clauses on liability and compensation in case the release of LMOs in the environment causes damage or risks to the conservation of biological diversity, human or animal health or life.[56]

2.4. An overview of the legislative developments in Brazil

As early as 1988, the Brazilian Constitution recognised the need to support environmental protection as a means of providing better standards of living for its population. The general constitutional principle, created by Article 225, *caput*, establishes that "[e]veryone has the right to an ecologically balanced environment, which is a public good for the people's use and is essential for a healthy life". Additionally, Article 225, *caput*, Brazilian Constitution, affirms that both the

---

[56]See, generally, information provided by UNEP Doc. N. UNEP/Bio.Div./Panels/Inf. 4, note 50, *supra*, pp.17-23.

government and the community "... have a duty to defend and to preserve the environment for present and future generations".

By establishing such a principle, the Brazilian Constitution acknowledges the value of environmental protection as a means of protecting the public interest in a higher quality of life for its population which is to be considered as beyond the discussion about economic development, focusing primarily on social development and duties.[57]

Several measures to be taken by governmental authorities are listed in Article 225 (1), Brazilian Constitution. Among others, the government must preserve the country's genetic patrimony and supervise "... the entities dedicated to research and manipulation of genetic material"[58]. Moreover, Article 225 (4), Brazilian Constitution, certifies that "[t]he Brazilian Amazon Forest, the Atlantic Woods, the Serra do Mar, the Pantanal of Mato Grosso, and the Coastal Zone are the national patrimony, and they shall be utilized, ... under conditions assuring preservation of the environment, including use of genetic resources".

Broadly speaking, the Brazilian constitutional principles establish the general guidelines for biodiversity protection and access to genetic resources. It is important to bear in mind that all Brazilian ecosystems, in their totality, are part of the patrimony of the country and their use shall be in accordance with the regulations implementing the constitutional principles. Regulatory mechanisms, however, must be created to

---

[57]See, generally, **José Afonso da Silva**, Curso de Direito Constitucional Positivo, São Paulo: Editora Revista dos Tribunais (1991), 7th ed., pp. 708-710.
[58]Brazilian Constitution, Art. 225 (1) (II).

interpret and control the use of the Brazilian environment in a way which leads to its preservation for present and future generations.

Considering its constitutional principles and the outcome of the UNCED, namely the CBD and the Agenda 21, the Brazilian federal government created in December 1994 the National Program for the Conservation and Sustainable Use of Biological Diversity (PRONABIO), under the institutional framework of the Ministry for the Environment and the Amazon Region, with the task of suggesting policy guidelines, legislative measures and institutional mechanisms to control the use of Brazilian biodiversity and the exploitation of its resources[59]. In spite of these institutional efforts, no regulatory proposals were suggested by the Brazilian federal government to Parliament. Current legislative developments within the Brazilian Parliament are the initiative of Members of Parliament themselves. At the moment there are two legislative Bills in the Brazilian Parliament dealing with access to genetic resources: PL N. 2.057, of 23 October 1991, on the Statute of Indigenous Societies, and PLS N. 306, of 9 November 1995[60], on instruments to control access to genetic resources. This Sub-section intends to highlight only the measures proposed by PLS 306/95. Further discussion on PL N. 2.057, of 23 October 1991, takes place in Section 3, Sub-section 3.3, Paragraph 3.3.2, *infra*.

---

[59]For this information see, **Ministry of Science and Technology**, SUSBIO: Sustainable Use of Biodiversity - A Strategy for the Use of Biodiversity Leading to Sustainable Development - Model Proposal for Brazil, *mimeo*, August 1994, p. 8.

[60]Hereinafter the "PLS 306/95".The acronym PLS stands for "Projeto de Lei do Senado", or legislative Bill which originated in the Federal Senate. PLS 306/95 was suggested by Senator Marina Silva, on 9 November 1995. Senator Marina Silva was awarded the Goldman Environmental Prize of 1996. This prize is regarded by many as the Nobel Prize for environmental issues (Time International, 29 April 1996, V. 147, N. 18).

In the justification to PLS 306/95, Senator Marina Silva explicitly affirms that the intention of this legislative Bill is to "... create a concrete space for discussion and decision-making about one of the crucial aspects of the biodiversity problem, which is access to genetic resources, ..."[61]. In doing so, Senator Marina Silva calls for the opening up of discussion on biodiversity prospecting between society, scientists, governmental and non-governmental organisations, Members of Parliament, and local and indigenous communities, in order to create a legal framework which is compatible with the sustainable use of biological diversity and with necessary Brazilian presence in the international debate[62].

PLS 306/95 is, therefore, divided in seven chapters, setting up general principles for the conservation and use of biological diversity, institutional mechanisms, regulatory measures to access genetic resources, the protection of traditional knowledge and the development and transfer of technology, and administrative penalties.

In its first chapter, entitled General Provisions, general principles to guide access to genetic resources are established. The government is therefore empowered to preserve the diversity, integrity and sustainable use of the "country's genetic patrimony"[63], as well as to monitor the work carried out by public and private entities dealing with research into and manipulation of genetic material[64]. This public task has to be conducted in the light of the following principles: (1) sovereignty and

---

[61]PLS 306/95, Justification, p. 6.
[62]*Ibid.*
[63]Which includes, by virtue of Article 3, PLS 306/95, all biological and genetic and maritime resources from the continental coast, and from Brazilian islands which are within the Brazilian territory, as well as to migrating species that are in the national territory because of natural causes.
[64]PLS 306/95, Art. 1, *caput*.

inalienability of the rights over the biological diversity and over the existing genetic resources in the national territory[65]; (2) participation of local communities and indigenous peoples in the decisions that have as their subject-matter genetic resources in the areas that they occupy[66]; (3) national participation in social and economic benefits arising from the use of genetic resources, particularly to benefit the local and indigenous communities involved[67]; (4) to give priority access to genetic resources for those who research them in the national territory[68]; (5) to promote and support the development of technologies in the country, giving emphasis to strengthening the national technological capacity[69]; (6) to provide protection and incentive for cultural diversity, particularly cultural diversity related to traditional knowledge and practices in connection with the conservation and sustainable use of biological and genetic diversity[70]; (7) to guarantee biosafety and the country's environmental and food-supply strategies[71]; and (8) to recognise knowledge associated with biodiversity, as a means of ensuring its protection and remuneration[72].[73]

Within this framework of principles, it is possible to identify three major groups of guidelines. Firstly, PLS 306/95 suggests the reaffirmation of the principle created by Article 15 (1), CBD, on the national sovereignty over genetic resources.

---

[65] *Ibid.*, Art. 1 (I).
[66] *Ibid.*, Art. 1 (II).
[67] *Ibid.*, Art. 1 (III).
[68] *Ibid.*, Art. 1 (IV).
[69] *Ibid.*, Art. 1 (V).
[70] *Ibid.*, Art. 1 (VI).
[71] *Ibid.*, Art. 1 (VII).
[72] *Ibid.*, Art. 1 (VIII).
[73] It is also worth mentioning that the provisions of PLS 306/95 shall apply to all natural or legal persons, national or international, which extract, use, store, commercialise or transfer genetic resources within the national territory (PLS 306/95, Art. 2). This law does not apply, however, to parts or genetic components of human beings and to the inter-exchange of biological resources

Additionally, the first principle listed by Article 1, PLS 306/95, emphasises the application of the sovereign rights principle by also stating that the rights over biodiversity are inalienable.

Secondly, this legislative Bill recognises, broadly, the application of the traditional knowledge and practices of local and indigenous communities by affirming that they shall participate in the decision-making process over genetic process in the territory they occupy, that social and economic benefits which arise from the exploitation of genetic resources shall be particularly shared by them when they are somehow involved, and by recognising their cultural diversity associated with the sustainable use of genetic and biological resources[74]. By accepting the need to guarantee individual and collective rights over knowledge related with biodiversity, recognising not only its protection but also its remuneration, PLS 306/95 also emphasises the need to protect the traditional knowledge and practices of local and indigenous communities as a means of accepting their constitutional rights[75].

The third characteristic of these principles is related to procedural aspects for the setting up of national strategies and policies in relation to the exploitation and use of biological and genetic diversity. By doing so, PLS 306/95 has recognised the two first group of principles which have been mentioned and also highlights the need for national participation in the economic and social benefits arising from the use of genetic resources. It also provides recognition of the necessity to have research on genetic resources taking place in the national territory, by giving priority to genetic

---

among indigenous communities, by their own means of communication, for their own ends and based on their customary practice (*Ibid.*, Art. 4).

[74] *Cf.*, PLS 306/95, Arts. 1 (II), (III) and (VI), respectively.

[75] *Cf.* PLS 306/95, Art. 1 (VIII).

resources to those who will carry on research in the national territory, and also by supporting the development of new technologies, giving emphasis to the development of national technologies, and providing principles on biosafety and national strategies related to environmental and food-supply issues.

Institutionally, PLS 306/95 approaches the subject by proposing the creation of a committee composed of representatives of the federal and state governments, the Federal District, the scientific community, non-governmental organisations and private entities. Such a committee would be empowered to co-ordinate, evaluate and assure the development of activities aiming at the conservation of the national genetic patrimony.[76] There are also several institutional tasks suggested by PLS 306/95, such as: (a) to produce a report in two years after the publication of this law regarding the level of threaten to biodiversity and concerning the potential impacts over sustainable development strategies of its destruction, such report to be up-dated once every five years; (b) to set up technical and scientific guidelines aiming at the establishment of priorities for the conservation of biodiversity; (c) to create a list of endangered genetic resources; (d) to create mechanisms for controlling and disseminating information on the national biodiversity; (e) to develop strategies and policies focusing on the conservation of biological diversity and on the sustainable use of it; (f) to control and prevent the introduction of alien species in the national territory; (g) to create mechanisms to consider the sustainable use or loss of biological resources as part of

[76]PLS 306/95, Art. 5 (I).

national accounting procedures; and (h) to identify priorities in the field of human resources related to the conservation and sustainable use of biodiversity[77].

The procedural aspects of access to genetic resources are set out by Chapter III of PLS 306/95. Article 6, *caput*, PLS 306/95, proposes to establish, firstly, a PIC mechanism for works aiming at the collection of biodiversity resources. Consent will be granted or refused after the following information is provided by the natural or legal person willing to collect resources: (a) detailed and specific information about the resource for which access is requested, including its actual or potential use, its sustainability and eventual risks that may occur as a result of the access; (b) detailed description of the methods, techniques, collection system and instruments to be used; (c) precise definition of the geographical area where collection of genetic resources will take place; and (d) indication of the place where the material collected will be taken and its probable posterior use[78]. In the case where access is requested for collection or research, and these resources are located in the territories of indigenous or local communities, PLS 306/95 calls for the establishment of regulations in this regard which will, at least, assure the hearing of the populations in question and the participation of at least one member of the community in the collection and research[79].

The respective national authority will then decide whether or not to grant authorisation for the required access[80]. If it decides to grant authorisation, it will be

---

[77]See, generally, PLS 306/95, Arts. 5 (II) to XII.
[78]PLS 306/95, Arts. 6 (I) to (IV).
[79]*Ibid.*, Art 6, Sole paragraph.
[80]Authorisation to access genetic resources does not imply that exportation of genetic resources is authorised (PLS 306/95, Art. 12). PLS 306/95 also determines that the transfer of alien genetic resources into the national territory is subject to authorisation of the competent authority (*Ibid.*, Art.

accompanied by the following obligations, listed as a minimum basis: (a) that the entity which has been granted access will be bound by national rules, particularly those related to sanitary control, biosafety, customs and environmental protection; (b) that the Brazilian federal government will have access, without restrictions, to all knowledge produced and to all information resulting from the research in question; (c) that Brazil will be given priority treatment to utilise the products which are the result of genetic resources; (d) that national participation in the economic, social and environmental results of the products and processes arising from the research based on genetic resources will take place; and (e) that those to whom access has been granted will deposit a sample of the genetic resource in question in a Brazilian institution[81]. The Brazilian authority in charge of access to genetic resources is empowered, together with the Brazilian technical-scientific institution assigned to follow the collection and the research[82], to make sure that the obligations set out in the authorisation are met[83]. The national authority may also request that the entity which is carrying out research based on and collection of genetic resources, should provide a study on the impact assessment as a result of the research or collection in

16). It is also worth mentioning that if genetic resources are collected or researched without formal authorisation, rights over collection and research will not be recognised by Brazilian national legislation, including IPRs (*Ibid.*, Art. 15).

[81]*Ibid.*, Art. 8. All research and collection of genetic resources in the national territory will be followed by a Brazilian scientific-technical institution with the scientific capacity in the area subject-matter of research, which will be assigned by the competent authority and will be deemed liable for the fulfilling of the obligations set out in the authorisation (*Ibid.*, Art. 7).

[82]*Cf.* PLS 306/95, Art. 7.

[83]PLS 306/95, Art. 9, *caput*.

question[84], as well as requiring financial compensation to the federal government for access to take place[85].

Article 17, *caput*, PLS 306/95, also suggests that the rights of local and indigenous communities should be recognised and protected, and that just compensation should be granted to these communities by using the mechanisms of intellectual property protection and others. It also recognises that, when it is not possible to identify individuals as holders of rights, collective rights over intellectual property protection will be used as a legal tool[86].

Traditional communities are also empowered to refuse access to genetic resources in their territory or in other area outside their territory. In the latter case, it will have to be proved that access to genetic resources in areas outside their territory will threaten the integrity of their natural and cultural patrimony[87].

PLS 306/95 also calls for two further measures to be taken in connection with the IPRs of local and indigenous communities. Firstly, it states that individual IPRs related to biological or genetic resources will not be recognised - registered either in Brazil or abroad - if they utilise the collective knowledge of traditional communities or if they are acquired without the authorisation for access or to export[88]. Secondly,

---

[84] *Ibid.*, Art. 9, Sole paragraph.
[85] *Ibid.*, Art. 10. The financial resources acquired from researchers on genetic resources, for access to be granted, will be deposited in the National Fund for the Environment (*Ibid.*, Art. 10, Sole Paragraph).
[86] *Ibid.*, Art. 17, Sole paragraph. By virtue of Article 18, PLS 306/95, the collective rights of traditional communities is a recognition of the rights traditionally acquired by, including industrial property rights, copyrights, breeders' rights, trade secret and others. These collective rights have to be implemented within one year counting from the date of publication of this law, under the following guidelines: (a) identification of the type of IPRs to be used in each case; (b) determination of the requirements and procedures for these rights to be recognised; and (c) creation of a registry system, procedures and rights and obligations of the right holders (*Ibid.*, Art. 19).
[87] *Ibid.*, Art. 20.
[88] *Ibid.*, Art 21.

PLS 306/95 suggests, in Article 22, that the government should review all patent or intellectual property rights based on Brazilian genetic resources which have been registered abroad, so that compensation may be claimed or a declaration of nullity may be obtained.

With regard to the transfer and development of technologies, PLS 306/95 affirms that the government shall promote and support the development of national sustainable technologies for use and advancement of species and varieties, giving priority to the traditional uses and practices of local and indigenous communities within the national territory, according to their own aspirations[89]. Alongside the support and promotion of the development of national technologies, the federal government may allow the utilisation of foreign biotechnology, as far as such use is in accordance with this law and national regulations on biosafety. The exporter of the technology in question must accept all responsibility for any damage caused to the environment, health and local cultures, in the present or in the future[90].

Article 25, PLS 306/95, calls for the creation of mechanisms to guarantee and facilitate access to and transfer of technologies which are relevant for the conservation and sustainable use of biodiversity to national researchers[91]. In the case of a transfer of relevant technologies which are capable of intellectual property protection, the government shall create conditions to guarantee that such transfer of and access to the technology in question will be in accordance with the adequate protection of IPRs[92].

---

[89] *Ibid.*, Art. 23. For the application of this principle a survey and evaluation of traditional and local biotechnology shall be carried out by the government (*Ibid.*, Art. 23, Sole paragraph).
[90] *Ibid.*, Art. 24.
[91] *Ibid.*, Art. 25.
[92] *Ibid.*, Art. 26.

Lastly, PLS 306/95 requires the federal government to establish a system of administrative penalties for those who infringes the rules on access to genetic resources. Such system should include, *inter alia*, the arrest of samples, materials and equipment utilised in the unlawful action, fines, and abrogation of the authorisation to access genetic resources[93]. These sanctions should not preclude the application of other civil or penal sanctions[94].

3. TECHNOLOGY TRANSFER AND IPRS IN THE CBD

The CBD regards technology transfer as a vital approach towards biodiversity conservation and sustainability. This is expressed by almost the entire text of the Convention and particularly emphasised by the CBD's Preamble:

> Acknowledging that the provision of new and additional financial resources and appropriate access to relevant technologies can be expected to make a substantial difference in the world's ability to address the loss of biological diversity,
>
> Acknowledging further that special provision is required to meet the needs of developing countries, including the provision of new and additional financial resources and appropriate access to relevant technologies, ...

The CBD has thus addressed all States, whether developed or developing economies, recognising that technology transfer is one of the major step towards biodiversity conservation. It has further accepted that a technological gap between developed and developing nations is evident by acknowledging that developing nations require special provision on access to technologies. Signatory States to the

---

[93] *Ibid.*, Art. 27.

CBD have therefore called for a broader form of assistance which includes scientific and technical co-operation.

Also in its Preamble, the CBD has recognised "... the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, ..." and further suggested that it is desired to share equitably the benefits arising from the use of traditional knowledge and practices of these communities. This leads one to understands that traditional knowledge and practices represent traditional technologies which are relevant for the conservation and sustainable use of biological resources.

Obviously, the implementation of the wording of the CBD's Preamble has given rise to more detailed provisions on this matter, which have been further considered in the text of the CBD and will be analysed in even more detail in the context of national rules aiming at implementing the biodiversity principles. This understanding leads naturally to discussions about the use of mechanisms to protect IPRs appropriately and effectively.

This link between traditional and modern technologies and intellectual property protection is probably the major issue of the CBD and has been subject to a controversial debate. The wording of the CBD is not detailed and leaves much discretion to national legislation. This appears to have posed a threat to the plans of major multinational companies, particularly in the biotechnological field, which have a great interest in the exploitation of genetic resources as a raw material for the research and development of new products.

---

[94] *Ibid.*, Art 27, Sole Paragraph.

A possible solution for building up scientific and technical capacities related to biodiversity conservation and sustainable use is by scientific and technical co-operation. By virtue of Article 18, CBD, this should take place by the development of national policies, training of personnel and exchange of experts, and by the promotion of joint research programmes and joint ventures for the development of technologies. The system suggested by Article 18 (3), CBD, to promote scientific and technical co-operation is the establishment of a clearing-house mechanism which would provide an information exchange service, serving as an instrument for the development of local, national and global policies, supporting the establishment of national institutional capacities, assisting countries to develop partnerships, and assisting the Executive Secretariat of the CBD by integrating and disseminating scientific, technological and technical information. In its first phase of operation, the clearing-house mechanism would give emphasis to the development of national capabilities, the facilitation of technology transfer , and the promotion of partnerships. It would thus operate as an accessible electronic data network, a decentralised network of national and regional centres, based as far as possible on existing institutions, using existing databases, information, services and networking capabilities. The Executive Secretariat of the CBD would be the international focal point of such a mechanism and responsible for gathering, organising and disseminating information of interest to the Contracting Parties and to the sustainable use of biological diversity.[95]

---

[95]UNEP Doc. N. UNEP/CBD/COP/2/6 (29 September 1995) Establishment of the Clearing-House Mechanism to Promote and Facilitate Technical and Scientific Co-operation.

3.1. Incentive to technology transfer with appropriate IPRs

An important step towards the implementation of the CBD's provisions on technology transfer is to ensure that Contracting Parties will have access to relevant information. It is, nevertheless, necessary to bear in mind that the intention of the CBD is not only to promote the exchange of information about specific technology, but also to promote and encourage the transfer of complete systems of technology such as know-how, goods and services, and organisational and managerial skills. This obviously includes both "hard" technologies, such as plant, equipment and computers, and "soft" technologies, such as know-how, skills, training and maintenance.[96]

Article 16 of the CBD attempts to create mechanisms to promote transfer of technology in a general way. This provision is probably the most controversial in the whole biodiversity debate and has raised several arguments from the US government, which has been strongly lobbied by its biotechnology industries. The ambiguous and imprecise wording of Article 16, CBD, reflects the complexity of the discussion in this field, which was determined as a result of the struggle between the interests of developing countries, which considered technology transfer to be a crucial element to the CBD, and the interests of developed countries strongly opposing the inclusion of technology transfer mechanisms to favour developing nations[97].

---

[96]UNEP Doc. N. UNEP/Bio.Div./Panels/Inf.3 (28 April 1993) Expert Panels Established to Follow-Up on the Convention on Biological Diversity - Technology Transfer and Financial Issues: Issues and Options from Panel III, p. 1, para. 1.2.

[97]**Lyle Glowka** *et al.*, note 35, *supra*, p. 84.

Taking into account that technology includes biotechnology[98], and that technology transfer among Contracting Parties is a vital element for the conservation and sustainable use of biodiversity, Article 16 (1), CBD, claims that Contracting Parties shall "... provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause damage to the environment".

It is firstly necessary to note that the wording of Article 16 (1), CBD, makes a suggestion rather than imposes an obligation. Contracting Parties shall "provide and/or facilitate" access to and transfer of technology. This provision does not necessarily impose an obligation on Contracting Parties to provide technology to other Contracting Parties, but proposes that mechanisms facilitating technology transfer should exist.

Also, while Article 16 (1), CBD, lists three types of technology for the purpose of technology transfer (technologies relevant to the conservation of biodiversity, technologies relevant to the sustainable use of biodiversity, and technologies that make use of genetic resources), it emphasises that such technologies shall not cause significant damage to the environment.

Access to and transfer of technology to developing countries, by virtue of Article 16 (2), CBD, "... shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanisms established

---

[98] *Cf.* Art. 2, CBD.

by Articles 20 and 21". Such access and transfer shall be in accordance and consistent with "... the adequate and effective protection of intellectual property rights". This provision shall be consistent with Articles 16 (3), (4) and (5), CBD.

Article 16 (2), CBD, is divided in three parts. The first part aims at creating more favourable conditions for developing countries access to and transfer of technologies. The second part requires access and transfer to be consistent with the protection of IPRs. The third part connects this paragraph with paragraphs 3, 4 and 5 of Article 16.

The first part of Article 16 (2), CBD, clearly recognises the lack of technological development of developing countries. Again, developed countries are not obliged to transfer and give most favourable terms of access to technology to developing economies, but technology access and transfer shall be "provided and/or facilitated" fairly and under most favourable terms. Developed countries, as holders of modern technologies, are thus not obliged to give such preferential treatment to developing economies. This probably suggests that such conditions will be put into practice once access to genetic resources is regulated under national legislation and a bargain type of relationship will take place. Developing countries will then authorise access to genetic resources that are present in their territory in exchange for access to and transfer of technologies. This technology transfer will obviously be mutually agreed between both parties.

The first part of Article 16 (2), CBD, also links access to genetic resources with the financial mechanisms of Articles 20 and 21, CBD. This necessarily implies that the institutional framework of the CBD may be used to provide funds for

facilitating access to and transfer of technologies to developing countries, aiding both parties to overcome the legal and economic difficulties included in the technology transfer.[99]

In the second part, Article 16 (2), CBD, requires that when technology which is the subject of transfer to developing countries is protected by IPRs, such protection shall be made effective and in accordance with the international mechanism of intellectual property protection. In this regard, it is necessary to mention that there are at least two situations in which IPRs are going to be dealt with. Firstly, the effective protection of technology which has been entirely developed by a natural or legal person or by a governmental institution, and which is transferred to a particular developing country, shall take place once such adequate and effective protection of IPRs over that technology is guaranteed. This is obvious, and transfer will not take place if such guarantee is not given. A second circumstance that raises more questions is that relating to a particular technology which has been developed by a natural or legal person, or governmental institution, based on genetic resources which are present in the national territory of the developing country in question. If authorisation was given by the latter, the terms of the authorisation of access to genetic resources will certainly contain clauses regulating IPRs as a result of research on genetic resources. However, if a natural or legal person, or governmental institution, has carried out research on a particular genetic material present in the territory of a developing country without the authorisation of the latter, IPRs over the result of such research will not arise. The developing country in question will certainly not

---

[99]**Lyle Glowka** *et al.*, note 35, *supra*, p. 86.

recognise intellectual property protection for such technology and will probably claim the nullity of IPRs on a national basis. For developing countries to claim the nullity of IPRs on an international basis, however, further multilateral mechanisms should be agreed to grant all countries with some necessary tools allowing them to claim international nullity of IPRs which are the result of research on genetic resources that were carried out without the authorisation of the provider country.

This leads to the third part of Article 16 (2), CBD, which calls for consistency of this provision with paragraphs 3, 4 and 5, of Article 16, CBD. Article 16 (3), CBD, requires Contracting Parties to take

> ... legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

Paragraph 3, therefore, addresses specifically the issues on technology transfer in connection with access to genetic resources. That is why it has been mentioned in the foregoing paragraph that the issues on IPRs will have to be consistent with the national measures - legislative, administrative or policy measures - regulating access to genetic resources and transfer of technology. It is also noteworthy that Article 16 (3), CBD, does not require measures only in developing countries in whose territory genetic resources are present. All Contracting Parties shall take measures in this regard, which highlights that the CBD has recognised that a two-party relationship will always occur in this regard and that measures shall exist on both sides. The CBD

has thus recognised that all Contracting Parties are potential providers and users of genetic resources and, "..., at least in theory, potentially entitled to receive technology making use of genetic resources"[100]. Article 16 (3), CBD, has in addition connected technology making use of genetic resources with the financial mechanism of the CBD, *i.e.* Articles 20 and 21, and required "mutually agreed terms"[101] to be the basis of transfer of technology based on genetic resources.

Legislative, administrative or policy measures are also required by the CBD, in Article 16 (4), "... with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries ...". By saying this the CBD has accepted the obvious: holders of modern technology, and particularly biotechnology, are mostly in the private sector of developed countries. The commitment reached by Article 16 (4), CBD, implies that the private sector which owns technology[102] will consider "access to, joint development and transfer of technology" if there are national measures which encourage such actions. These measures are particularly relevant when arising in developing countries, but the wording of this paragraph suggests that measures are necessary in all Contracting Parties, whether exporters of technology or providers of genetic resources. It seems, therefore, that some degree of co-ordination is necessary to make such a provision prevail, with encouragement from developed countries which need genetic resources as a raw material for research and development and the

---

[100] *Ibid.*, p. 90.
[101] *Cf.* Section 2, Sub-section 2.2, *supra*.

necessary obligations created by national legislation of developing countries which need to develop their technological capacity in order to conserve biodiversity. At the end of the day, the letter of Article 16 (4), CBD, proposes measures which are of interest for both providers and users of genetic resources.

Article 16 (5), CBD, finally makes an incisive statement towards the protection of IPRs, by recognising that patents and other IPRs may have influence on the implementation of the CBD and by inviting Contracting Parties to co-operate in order to ensure that IPRs are supportive of and do not run counter to the objectives of the Convention. As mentioned by Lyle Glowka[103], this paragraph suggests that Contracting Parties to the CBD have not concluded whether IPRs have a positive or a negative impact over biodiversity conservation. Co-operation among Contracting Parties is therefore suggested as a means of agreeing upon the necessary measures on intellectual property protection which are supportive of and do not run counter to the goals of sustainable use and conservation of biological diversity, and equitable and fair sharing of the benefits arising from the use of biodiversity. Such co-operation is indeed necessary and unavoidable if a balance between economic and environmental interests is to be reached. The US government, however, has suggested that the wording of Article 16 (5), CBD, leads one to interpret the Convention as giving "... Contracting Parties authority to restrict or ignore intellectual property rights"[104]. This does not seem to be the case. Article 16 (5), CBD, clearly affirms that such co-operation shall be subject to national legislation and international law. The latter has

---

[102]The technology referred to here is threefold: technology relevant for conversation, technology relevant for sustainable use, and technology which makes use of genetic resources. This is a consequence of the reference made to Article 16 (1), CBD.
[103]Note 35, *supra*, p. 91.

as a basis the TRIPS Agreement which proposes a minimum basis of protection in accordance with US interests. Of course, if IPRs would somehow run counter to the objectives of the CBD, Contracting Parties may consider not granting protection for inventions which are not environmentally friendly

3.2. Biotechnology, participation in research and sharing of benefits

Although Article 19, CBD, does not refer explicitly to the protection of intellectual property, it does contain obligations about the participation of countries providing genetic resources in biotechnological research and the sharing of results and benefits of such research, paying particular attention to developing countries.

Article 19 (1), CBD, requests each Contracting Party to "... take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide genetic resources for such research". It also requires that biotechnological research using genetic resources should, where feasible, take place in the provider country.

There are two characteristics of Article 19 (1), CBD, to be looked at in more detail. By suggesting the participation of Contracting Parties which provide genetic resources in the biotechnological research using those resources, the CBD aims at encouraging the building up of human capacity in the provider country. This leads to several positive consequences for these countries, such as the development of a community of scientists trained particularly in relation to national genetic resources

---

[104] **Joseph Straus**, note 23, *supra*, p. 607.

which as a consequence may lead to the training of other researchers of that particular country by those who have participated in the biotechnological research. This all may lead to the creation of the countries' own technological capabilities and, as a consequence, to the development of biotechnological products for the local, national or global markets. The letter of Article 19 (1), CBD, is extremely direct when it requires "effective" participation of the countries providing genetic resources in the biotechnological research. By contrast with the wording of Article 15 (6), CBD, which requires Contracting Parties to encourage the participation of the countries providing genetic resources, Article 19 (1), CBD, makes a strong claim for such participation.

The second characteristic of Article 19 (1), CBD, is that biotechnological research should, where feasible, take place in the territory of the country providing the genetic resources. This suggests that the CBD has accepted that when research takes place in the territory of the provider country, particularly when such a country is a developing one, it may involve transfer of "hard" technologies such as laboratory equipment necessary for biotechnological research. When the research is concluded, this equipment may, depending on the terms of the access agreement, stay in the provider country, helping the latter to develop its own capacities and train other researchers by using such equipment. Also, the participation of researchers from the provider country may be in larger numbers if it takes places in the territory of this country.

Article 19 (2), CBD, also requires all Contracting Parties to take measures "... to promote and advance priority access on a fair and equitable basis by Contracting

Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties". This access must be on mutually agreed terms.

This provision acknowledges, by accepting that benefits exist, that genetic resources have a commercial, economic and scientific value, entitling the Contracting Parties providing such resources to have priority access to the results and benefits, on a fair and equitable basis and on mutually agreed terms.

The expression "priority access" is not defined by the Convention but seems to imply a preferential treatment for those countries providing genetic resources in the sharing of the results and benefits of biotechnological research. Neither "Results" nor "benefits" are defined by the CBD. It seems that this is to be defined by national legislation or access agreements. "Benefits", however, seems to be a broad concept and may be applied to a variety of consequences of biotechnological research. Some commercial benefit may arise from products developed by biotechnological research. These products (the results) will certainly be commercialised. National legislation or access agreements will thus provide for the payment of royalties to the provider country as a means of benefit-sharing. Also, scientific results may be of interest to developing countries which are the providers of genetic resources and mechanisms are to be created by national law or access agreements to guarantee effectively the participation of the such country in the benefits. Scientific benefits are broad and could include the training of personnel, access to technology (both hard and soft) and the maintenance of laboratory equipment. The vague wording of the CBD, however,

leaves discretion to national legislation and access agreements to define how these terms are to be implemented and applied.

3.3. Traditional practices and knowledge

The traditional concept of IPRs has been broadened substantially in accordance with the developments of new technologies and needs of modern society.[105] After the commitments achieved by the UNCED, namely the CBD, another aspect of intellectual property protection was raised. The CBD, in its Preamble recognises that it is desirable that the "... benefits arising from the use of traditional knowledge, innovations and practices ..." of indigenous and local communities should be shared equitably.

Later on, Article 8 (j), CBD, establishes a broader intellectual property principle, when says that national laws shall, as far as possible and as appropriate,

> respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying their traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holder of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

It is firstly necessary to understand that the CBD clearly accepts that the knowledge, innovations and practices of local and indigenous communities are relevant to the conservation and sustainable use of biological diversity[106]. Two other

---

[105]At the international level, several efforts have been made to harmonise intellectual property protection. See, for further information, Chapter 2, *supra*.

[106]The importance of traditional knowledge for the conservation and sustainable use of biological diversity is supported by the CBD in two other provisions. The Preamble affirms that "... traditional

important points on the application of this international principle, however, must be considered. Firstly, it is necessary to say that the CBD claims that traditional knowledge, innovations and practices of local and indigenous communities have a commercial value, once it is accepted that benefits arise from the utilisation of such traditions, and that these benefits are to be shared. Also, the CBD determines a link between sustainable development and commercial value within the traditional concept of IPRs. The CBD even utilises the vocabulary typically used for the definition of the proprietor of an intellectual property right when it entitles local and indigenous communities to be the holders of their knowledge, innovations and practices. In my opinion, it is possible to interpret the wording of the CBD as including the traditional practices and knowledge of local and indigenous communities within the current system of national and/or international intellectual property laws. After all, the international community has considered such problems and further has included its understanding of this matter in the text of the CBD. The discussion in this field is widening in a legal sense and further commitments and principles may be created in the near future.

3.3.1. A sui generis system and the TRRs concept

The "Western" concept of proprietorship and commercial value has been applied to protect tangible and intangible manifestations of human society. The legal instrument

---

knowledge, innovations and practices [are] relevant to the conservation of biological diversity and to the sustainable use of its components". Moreover, Article 17 (2), listing the type of information that may be relevant, for exchange purpose, to the conservation and sustainable use of biodiversity, includes "... indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1".

traditionally used for this purpose is IPRs. Phillips and Firth[107] have suggested that the traditional concept of IPRs could be defined in two ways: (a) in a colloquial sense, IPRs include everything which emerges from the exercise of the human brain; and (b) in a legal sense, IPRs are understood as "... the legal rights which may be asserted in respect of the product of the human intellect".

The application of these legal rights, however, is costly and complex in technical terms. The development of technologies has led to a broader approach towards intellectual property protection, developing new legal mechanisms, concepts and principles which could include the technological development of contemporary society. Until recently, however, the traditional knowledge, innovations and practices of local and indigenous communities were not considered to be capable of legal protection. But the CBD has formally accepted such a concept, raising doubts concerning the legal instrument that could be used to implement the principle created by Article 8 (j), CBD.

As the lifestyle of local and indigenous communities has relevant qualities and assets for genetic resources prospecting, the issues of whether intellectual property rights include traditional practices, innovations and knowledge was raised. Industries which deal primarily with modern technology, particularly biotechnology industries, have a growing interest in traditional knowledge and practices[108] and this has, even more effectively, raised concerns about how to include traditional lifestyles under

---

[107] **Jeremy Phillips & Alison Firth**, Introduction to Intellectual Property Law, London, Dublin and Edinburgh: Butterworth & Co (Publishers) Ltd. (1990), 2nd ed., p. 3.

[108] **Stephen R. King**, The Source of Our Cures, [1991] *Cultural Survival Quarterly* 19-22, at p. 19, estimates that "[r]oughly 74 per cent of the 121 plant-derived compounds currently used in the global pharmacopoeia have been discovered through research based on ethnobotanical information on the use of plants by indigenous people".

legal protection, to secure benefit-sharing, conservation and sustainable development of biological diversity.

Several international gatherings on this subject have taken place among scientists, indigenous and local communities themselves, ecologists and ethnobiologists, and a conclusion is that IPRs will not assure protection for the variety of rights included in the lifestyle of traditional societies.

Aware of these difficulties and of the need to discuss further a legal mechanism that could be used to protect the rights of indigenous and local communities, a Working Group on Traditional Intellectual, Cultural and Scientific Resource Rights (or the Working Group on Traditional Resources Rights)[109] has developed a concept that could be used for the protection of all these rights of indigenous and local communities in a single instrument, with *sui generis* characteristics, and entitled "Traditional Resource Rights" (TRRs).

Posey and Dutfield[110] define TRRs as such:

> ... the term "traditional resource rights" (TRRs) was adopted to reflect the necessity of rethinking the limited and limiting concept of IPRs. The term "traditional" refers to the cherished practices, beliefs, customs, knowledge, and cultural heritage of indigenous and local communities who live in close association with the Earth; "resource" is used in its broadest sense to mean all knowledge and technology, aesthetic and spiritual qualities, tangible and intangible sources that, together, are deemed by local communities to be necessary to ensure

---

[109]In 1989, the International Society for Ethnobiology's "Declaration of Belem" called for the development of effective strategies to stimulate the responsible use of traditional knowledge and "biogenetic" resources to benefit indigenous and local communities, while securing self-determination for these peoples. As a result, a "Working Group on Intellectual Property Rights" was established. After, the Working Group was renamed "The Working Group on Traditional Intellectual, Cultural and Scientific Resource Rights" to reflect the broadened scope of the subject.

[110]**Darrell Posey & Graham Dutfield**, Beyond Intellectual Property Rights: Towards Traditional Resource Rights for Indigenous and Local Communities, Gland/Switzerland and Ottawa: WWF-International & IDRC (forthcoming).

> healthy and fulfilling lifestyles for present and future generations; and "rights" refers to the basic inalienable guarantee to all human beings and the collective entities in which they choose to participate of the necessities to achieve and maintain the dignity and well-being of themselves, their predecessors, and their descendants.[111]

The concept of TRRs has thus emerged to define the variety of rights that may protect the rights of local and indigenous communities, aiming, at the same time, at the conservation and sustainable use of biological diversity, and respect for the lifestyles and basic human rights of these societies. TRRs, therefore, includes plants, animals, and other objects that may have material, sacred, ceremonial, or aesthetic value to indigenous communities. So far, the concept of TRRs has defined eighteen binding and non-binding principles of international law that may be utilised to form the basis of the concept. Among others, one will find the principle of human rights, IPRs and neighbouring rights, the right to self-determination, the right to privacy and prior informed consent, rights to protection of cultural property, folklore and cultural heritage, recognition of customary law and practice, and farmers' rights[112].

From the application of all these rights together, a *sui generis* system could be created and the application of intellectual property principles would be included within a broad concept and therefore adapted to the specific circumstance of indigenous and local communities. It appears, however, that the execution of such a concept, as a means of implementing Article 8 (j) of the CBD, by national legislation would only limit the possible enforcement and application of these rights. A multilateral agreement in this regard seems to be the most effective way to protect the traditional

---

[111] *Ibid.*, Introduction, in *http://www.idrc.ca/books/799.html*.

rights and practices of local and indigenous communities. Multilateral negotiations, would however have to consider the views of indigenous and local communities and their own concepts towards an international agreement in this field.

3.3.2. An overview of the legislative developments in Brazil

Although provisions on the protection of indigenous rights have been in the Brazilian legal framework for more than three centuries[113], they have rarely been effective in practical terms.

At the beginning of the 1970s Law N. 6001 , of 19 December 1973 (Law 6001/73), was created to set up a basic principle of indigenous rights and institutional mechanisms for the application and enforcement of these rights. Among other principles, Law 6001/73 determined that all laws of Brazil apply to indigenous communities and individuals as it is applied to all Brazilians, but their traditions, customs, practices and particular conditions shall be respected[114]. However, taking into account the juridical understanding of the application of indigenous rights at that time, such respect to the indigenous' customs, practices and traditional lifestyles did not take place effectively.[115]

---

[112]For a comprehensive list of the "bundle of rights" that are included in the TRRs concept, see Appendix V, *supra*.

[113]**José Afonso da Silva**, note 57, *supra*, at p. 719, advises that already in the colonial period the rights of indigenous communities over the land they have traditionally occupied has been a mechanism of Brazilian/Portuguese colonial legal framework: Charter of 1 April 1680, followed and confirmed by Law of 6 June 1755.

[114]Law 6001/73, Arts. 1, Sole paragraph and 2 (VI).

[115]Article 6 of the Brazilian Civil Code (Law N. 3071, of 1 January 1916, and amendments, published in **Juarez de Oliveira** (organiser) Código Civil, São Paulo: Editora Saraiva (1987) 37th ed.) states that the silvicolous were "relatively uncapable" of exercising some judicial acts (at Art. 6 (III)) and that they were subject to a tutelage regime (Art. 6, Sole paragraph).

Following the above mentioned period, the Brazilian Parliament, gathered as a "constitutional convention", promulgated a new Brazilian Federal Constitution on 5 October 1988, opening the way for the country's redemocratisation. The 1988 Brazilian Constitution exposes the legislature's great effort to set up constitutional principles which could effectively protect indigenous peoples' rights and interests.

Article 231, *caput*, Brazilian Constitution, affirms that "[t]he social organization, customs, languages, creeds and traditions of Indians are recognized, as well as their original rights to the land they traditionally occupy"[116]. Further, it establishes that the lands that indigenous communities have traditionally occupied "... are destined for their permanent possession, and they shall be entitled to the exclusive usufruct of the riches of the soil, rivers and lakes existing thereon"[117].

Firstly, it is necessary to recall that the Constitution refused to use the expression "indigenous nations", based on the controversial premise that the expression "nation" has a strict understanding that a nation is an independent country with sovereign rights[118]. Secondly, it is remarkable that indigenous communities were recognised as such, with the debate going beyond the question on land rights, embracing also rights related to their creeds, customs, traditions and practices. Implementing legislation shall thus regulate the collective rights owned by indigenous communities taking into consideration that constitutional provisions defined two basic rights over those lands: the right of permanent possession and the right of usufruct.

---

[116]"Lands traditionally occupied by Indians are those on which they live on a permanent basis, those used for their productive activities, those indispensable for the preservation of environmental resources necessary for their well-being and those necessary for their physical and cultural reproduction, according to their uses, customs and traditions" (Brazilian Constitution, Art. 231 (1)).
[117]Brazilian Constitution, Art. 231 (2).
[118]**José Afonso da Silva**, note 57, *supra*, p. 715.

The permanent possession of the lands that indigenous communities have traditionally occupied is necessarily a broad concept. It should not be understood only as the *ius possessionis*, but also as the *ius possidendi*, because this exposes also the right to possess the *res* with a legitimate legal character of contiguous utilisation.[119]

The exclusive usufruct of the wealth of the soil, rivers and lakes existing thereon represents a civil law concept that grants a person (the usufructuary) the right to enjoy the fruit or profits of property that is owned by another and the duty to maintain the substance of the property.[120]

In addition, all acts aiming at the occupation, dominion and possession of the lands traditionally occupied by indigenous communities, "... or at the exploitation of the natural wealth of the soil, rivers and lakes existing thereon, are null and void, producing no legal effects ..."[121].

Finally, the Brazilian Constitution has provided that Indians, their communities and their organisations have the right to sue and to defend their rights and interests, with the Public Ministry intervening in all stages of the procedure[122]. The Public Ministry is a permanent institution, constitutionally considered essential for the functioning of the judicial system, with the duty of defending the legal order, democracy and social and individual rights[123]. The Public Ministry, among other

---

[119] *Ibid.*, at p. 720.
[120] The lands that are occupied by indigenous peoples are the property of the Brazilian State, pursuant to Article 20, XI, Brazilian Constitution.
[121] Brazilian Constitution, Art. 231 (6).
[122] *Ibid.*, Art. 232.
[123] *Ibid.*, Art. 127, *caput*.

functions, has the "institutional function" of defending the rights and interests of indigenous populations[124].

Though not very clear, it is possible to interpret Brazilian constitutional provisions as protecting the intangible rights of indigenous communities and individuals. Nevertheless, the details of this interpretation shall be worked out by national authorities and by national courts, aided by the provisions arising from secondary legislation in this matter. Thus, following an old expression *nemo iudex sine actore* (that the judge will decide upon a case only if he is required to), case law may play an essential role in the development of judicial concepts designed to protect indigenous intangible rights and, as a consequence, to regulate one of the tools for prospecting biological resources.

The Brazilian Parliament has been negotiating further developments of the rules governing the rights of indigenous communities. In 1991, five Brazilian Members of Parliament proposed a Bill, PL N. 2.057, of 23 October 1991 (PL 2057/91)[125], which aims to update national legislation regulating indigenous rights[126]. PL 2057/91 suggests several novel and important provisions concerning the

---

[124]*Ibid.*, Art. 129 (V).

[125]PL is the acronym for "Projeto de Lei" or, legislative Bill, in English. Five other legislative Bills were attached to PL 2057/91 - PL 4916/90, PL 2451/91, PL 2160/91, PL 2619/92 and PL 4442/94 - and, with the exception of the latter, all suggested mechanisms to protect traditional knowledge, innovations and practices. A Special Committee has been created to analyse the subject and to decide upon amendments or modifications to the proposed texts. Hereinafter, when this paper refers to PL 2057/91, it means the version approved by the Special Committee on 15 June 1994, and which has considered the attached proposals. PL 2057/91 will be sent to the Federal Senate for consideration. It will then return to the Chamber of Deputies which will decide upon probable amendments made at the Federal Senate. Only after the Chamber of Deputies approves or modifies the version sent back by the Federal Senate, the Bill goes to the President for sanction.

[126]The legislation currently into force in Brazil is Law 6001/73. When PL 2057/91 becomes legally applicable (Article 174 of PL 2057/91 says that it will enter in force at the date of publication in the Brazilian Official Journal), Law 6001/73 will be automatically revoked (PL 2057/91, Art. 175).

protection of indigenous rights and, in particular, those regarding their intellectual rights. These provisions are the subject of the following discussion.

PL 2057/91 initially addresses some procedural questions and states that the indigenous communities have legal personality and that their legal existence does not depend upon any type of registration or any act of government[127]. Further, it recognises all civil, political, social and labour rights, as well as the fundamental rights and guarantees of the Brazilian Constitution[128]. PL 2057/91 further lists, in Article 14, what constitutes indigenous assets, including author's rights[129] and industrial property rights[130].

Title II, Chapter II, PL 2057/91, suggests legal tools designed to protect traditional practices and knowledge, undoubtedly aiming at the implementation of the provisions of the CBD which has been referred throughout the present analysis. It also determines criminal and civil responsibilities, provisions on enforcement, juridical application of these rights and substantive aspects of industrial property protection.

It also proposes a new concept for the application and patentability of indigenous industrial property rights, when it establishes a principle for the protectability of indigenous traditional knowledge which is not capable of patent protection.

---

[127]PL 2057/91, Art. 8. **Andrée Lawrey**, Contemporary Efforts to Guarantee Indigenous Rights Under International Law, [1990] 4 *Vanderbilt Journal of Transnational Law* 703-777, at p. 714, stresses that the positivist approach to international law has traditionally denied legal personality to indigenous communities.

[128]*Ibid.*, Art. 9. Note that, amongst the fundamental guarantees and rights, as established by Brazilian Constitution, there are author's rights (Art. 5 (XXVII)) and industrial property rights (Art. 5 (XXIX)).

[129]*Ibid.*, Art. 14 (IV).

[130]*Ibid.*, Art. 14 (V).

(a) Patentable subject-matter

In the first place, PL 2057/91 determines that indigenous communities have the fundamental right to maintain the confidentiality of the traditional knowledge they possess. This will apply, in particular, to knowledge about the characteristics and properties of ecosystems and natural habitats, living species, plants or animals, micro-organisms, pharmaceuticals and natural essences, or any biological or genetic processes.[131] Further, Article 18 (1) suggests, on a minimum basis, that the rights above-listed include the right to refuse, without any justification, access to their traditional knowledge. They may also refuse to authorise the disclosure or utilisation of their traditional knowledge, for scientific, commercial or industrial purposes. As a matter fact, any violation of the fundamental right established by Article 18, *caput*, will be subject to criminal[132] and civil[133] responsibilities[134].

Note that, before considering further the issues on industrial property protection of indigenous knowledge, Article 18, PL 2057/91, established a new principle in the field of industrial property protection, explicitly recognising that their knowledge is particularly important in the pharmaceutical and biotechnological fields.

---

[131] *Ibid.*, Art. 18, *caput*.

[132] Title VII, PL 2057/91, sets up general principle of penal law and lists the crimes against the Indians and the respective penalties. Articles 157 and 158 are of particular interest to the present analysis. Article 157 considers it a crime to utilise, commercially or industrially, genetic or biological resources, in the indigenous peoples lands, without the previous written consent of the indigenous society which owns that land. Article 158 considers it a crime to utilise, commercially or industrially, directly or not, traditional indigenous knowledge, patentable or not, without the previous written consent of the indigenous society which has the permanent possession of the traditional knowledge in question.

[133] Civil responsibilities will be governed by Brazilian Civil Code, note 115, *supra*, and includes any moral and/or material damages against indigenous societies.

[134] PL 2057/91, Art. 18 (2).

Further, it is established that indigenous communities, or any of their members, have the right to apply for a patent of invention, utility model, industrial model or industrial design which has been developed utilising their traditional collective knowledge[135]. The patent will be always granted under the name of the respective indigenous community and, as a consequence, will be considered null and void if granted individually[136].

It is also established by PL 2057/91 that the access, utilisation and application of indigenous traditional rights in scientific research aiming at industrial or commercial ends will be allowed only with the previous written consent of the indigenous community[137]. The consent in question shall have the form of a written contract[138], drafted with the legal assistance of the Public Ministry, in which the specific contractual conditions will be determined, including a just and equitable share of the industrial or commercial benefits of the results of the research[139]. All the information that has been provided by the indigenous communities during the negotiations of the contract, which includes indigenous knowledge, will be considered confidential and will require previous authorisation from the community to be transmitted to someone else[140].

Also, the current version of PL 2057/91 considers that the indigenous communities will be deemed automatically co-proprietors of any invention, utility

---

[135]*Ibid.*, Art. 19, *caput*.
[136]*Ibid.*, Art. 19 (1).
[137]*Ibid.*, Art. 20, *caput*. *Cf.* Art. 157.
[138]*Cf.* PL 2057/91, Art. 46, which states that any type of contract between an indigenous community and a foreign person, entity or undertaking will be supervised by the Brazilian government who will defend, coraterally, the interests and rights of the respective communities in the national and international forum.
[139]PL 2057/91, Art. 20 (1).

model, industrial model or industrial design which has utilised, directly or indirectly, their traditional knowledge or models.[141] Taking that into account, anyone who applies for a patent based on traditional knowledge or model must mention which indigenous community shall be included as co-proprietor of the patent[142].

This part of PL 2057/91 also refers to several procedural and administrative rules which shall be briefly considered. Firstly, it is important to bear in mind that all acts aiming at the commercial or industrial use of indigenous knowledge or model will be deemed null and void if there is no written authorisation of the indigenous community in question and/or if the co-proprietorship of the patent is not considered in the contract[143]. Secondly, the fees related to the patent application and maintenance of the rights do not apply to indigenous communities[144], but in the case of a co-proprietorship, the other patent owner, if not an indigenous community, will be liable to pay the full amount of the fees[145]. Also, most of the requirements in question do not apply to pure scientific research which has no aim of profit[146].

It is important to remark also that the indigenous communities may request, administratively or judicially, the declaration of nullity of a patent or model, which has been based on indigenous traditional knowledge or model, contrary to the provisions of this law[147]. Brazilian administrative or judicial[148] authorities will have exclusive

---

[140]*Ibid.*, Art. 20 (3).
[141]*Ibid.*, Art. 21, *caput*.
[142]*Ibid.*, Art. 21 (1).
[143]*Ibid.*, Arts. 19 (1), 20 (4), 21 (1) and 22, Sole paragraph.
[144]*Ibid.*, Art 19 (2).
[145]*Ibid.*, Art. 23.
[146]*Ibid.*, Art. 29.
[147]*Ibid.*, Art. 22, *caput*.
[148]According to Article 109 (XI) of the Brazilian Constitution, the Federal Justice has exclusive jurisdiction to decide upon any dispute on indigenous rights. PL 2057/91, in Article 25, Sole

jurisdiction to resolve any dispute related to judicial acts regarding the intellectual property rights of indigenous communities[149].

(b) Non-patentable subject-matter

A single provision of PL 2057/91 is the one which proposes more effective understanding of industrial property issues in connection with indigenous knowledge, practices and innovations. As has been briefly mentioned before, indigenous traditional knowledge and models do not quite fulfil the requirements of patentability, in particular those related to the state of the art and its consequent legal novelty. It is possible that administrative and juridical interpretation of existing laws could apply patent principles taking into account the particular characteristics of indigenous traditional knowledge and practices.

PL 2057/91 has therefore proposed in Article 28 that the protection determined by Chapter II, Title II, PL 2057/91, includes traditional indigenous knowledge about characteristics or properties of ecosystems, natural habitats, living species, plants or animals, micro-organisms, pharmaceuticals and natural essences, or any biological or genetic process or application, which is not capable of patent protection. In simple words, the national legislature has defined the broad application of indigenous rights. It has, nevertheless, forgotten to define which legal mechanism will be provided for the protection of non-patentable subject-matter. It is a matter that

---

Paragraph, and Article 56, repeats the constitutional provision giving exclusive jurisdiction to the Federal Justice to decide upon such disputes.

[149]PL 2057/91, Art. 25, *caput*.

will certainly be considered in more detail after the law is interpreted by administrative authorities[150].

It seems that the national legislature decided to create a legal mechanism to include the broad application of indigenous knowledge under legal protection. This new industrial property principle will probably lead national patent offices to create administrative jurisprudence on the analysis of the conditions of a patent application which includes the utilisation of indigenous knowledge. Consequently, national judges will be bound to consider the broad application of indigenous communities' intellectual property principles when deciding upon disputes.

(c) Copyrights

The issues of copyright protection over the intellectual productions or spiritual creations of indigenous communities is also discussed extensively by PL 2057/91. Indigenous communities are therefore considered the owners of the moral and economic rights over intellectual productions and spiritual creations which have been produced collectively and performed somehow[151]. It is noteworthy that PL 2057/91

---

[150]In the case of Brazil, the authority with the functions of analysing and granting patents, as well as deciding upon administrative appeals, is the National Institute of Industrial Property (INPI), created by Law N. 5.648, of 11 December 1970.

[151]PL 2057/91, Art. 31, *caput*. Further, Articles 31 (I) to (VII) lists exhaustively examples of intellectual property rights of indigenous communities, and in Article 31 (VII) it emphasises that any other intellectual production or spiritual creations of indigenous communities are protected, even if they have been transmitted orally, independent of its origin in time. In the case of intellectual production or spiritual creations which have been developed individually, the provisions of Law N. 5.988, of 14 December 1973, which regulates authors' rights, will apply.

considers the protection of both the economic[152] and the moral[153] rights over these intellectual productions.

Thus, any form of reproduction, utilisation or communication to the public, directly or indirectly, by any means, of indigenous collective creations is allowed only with the express written authorisation of the community in question[154]. This authorisation will have the form of a written contract, done with the legal assistance of the Public Ministry, and in which will be included the authorisation to divulge the intellectual production which is the subject-matter of the contract, as well as the just and equitable payment to the community in question[155] and the other terms of the contract[156].[157]

PL 2057/91 also considers that the reproduction, application, publication or communication to the public - by any form, process or means - of indigenous intellectual creations, for the purposes of education, information, scientific studies or

---

[152]The economic rights are those which entitle the author to authorise reproduction, translation or adaptation of his work, as well as its public performance, against the appropriate payment of royalties.

[153]Article 6*bis* (1), Berne Convention, defines moral rights as those which entitle the author to claim authorship of his work and to object to modifications or mutilations of his work which would be prejudicial to his honour or reputation. It further emphasises that moral rights continue to exist even after the author has transferred his economic rights. Conversely, Article 9 (1), TRIPS Agreement, says that "... Members shall not have rights or obligations under this [TRIPS] Agreement in respect of the rights conferred under Article 6*bis* of that [Berne] convention or of the rights derived therefrom".

[154]PL 2057/91, Art. 38, *caput*. *Cf.* Art. 37 which says that indigenous communities have all the rights to use their intellectual and/or spiritual creations themselves, and also the right to authorise their utilisation by third parties.

[155]*Ibid.*, Art. 38 (1).

[156]*Ibid.*, Art. 38 (2). If the contract does not mention the duration of its obligations, it will be deemed null.

[157]Note also that it is recognised that indigenous communities have the right to manage the financial resources received for their authors' rights (PL 2057/91, Art. 38 (3)).

charity, without profit ends, will not be considered to be against the provisions established by PL 2057/91[158].

Some institutional mechanisms for the protection of indigenous intellectual production are also created by PL 2057/91. Firstly, it is established that the federal organ responsible for indigenous matters will provide free service for the registration of the intellectual productions or creations of indigenous communities[159]. The indigenous federal organ will also have other tasks such as the arbitration of disputes over indigenous intellectual property rights[160] and all the administrative structures for the protection of authors' rights of indigenous communities, including a funding mechanism[161].

4. A POSSIBLE OUTCOME OF THE WTO SYSTEM

The results of the Uruguay Round of negotiations of GATT are also relevant to the present discussion. The conclusions of the Uruguay Round have re-modelled the international trade system and agreed upon the most comprehensive set of regulations on intellectual property protection.

In addition to the institutional structure described in Chapter 2, Section 2, *supra*, the Ministerial Meeting of the GATT in Marrakesh, held on 14 April 1994,

---

[158]PL 2057/91, Art. 40 (I). Also, the quotations of indigenous productions in books, articles, periodicals or other type of academic analysis are allowed, pursuant to Article 40 (II). In any case, the name of the community, author of the work, has to be acknowledged and a copy of the work has to be sent to the community (*Ibid.*, Art. 40, Sole paragraph).

[159]*Ibid.*, Art. 34, *caput*. Note, however, that this registration is not compulsory for the purposes of validity and application of the indigenous' rights provided by PL 2057/91 (*Ibid.*, Art. 34 (4)).

[160]*Ibid.*, Art. 34 (1) (V).

[161]*Ibid.*, Art. 34 (1) (VII), and Arts. 34 (2) (I) and (II).

adopted a Decision on Trade and Environment[162] which calls for the establishment of a Committee on Trade and Environment (CTE) open to all Members of the WTO. The CTE shall initially address "... the relationship between the provisions of the multilateral trading system and trade measures for environmental purposes, including those pursuant to multilateral environmental agreements"[163], *inter alia*, and "... will consider ... the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights as an integral part of its work, ..."[164].

As a consequence, the analysis of the relevant provisions of the TRIPS Agreement, together with the analysis of the relationship between the WTO and multilateral environmental agreements, might lead the CTE to discuss the provisions of the CBD which deals with access to genetic resources, access to and transfer of technology, biotechnology, and the protection of the rights of local and indigenous communities. In fact, it seems that the CTE has already started to consider several issues in the context of environmental protection and its relationship with the TRIPS Agreement[165]. Although this discussion is still at a very early stage within the WTO

---

[162]**GATT**, The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts, Geneva: GATT Secretariat (1994), pp. 469-471.

[163]*Ibid.*, p. 470.

[164]*Ibid.*, p. 471. From the announcement of the first drafts of the Final Act up to 1994 Decision on Trade and Environment, note 162, *supra*, discussions of environmental issues were generally unsatisfactory. However, at the end of the Uruguay Round of negotiations there was an agreement on the terms of reference for the development of a work programme on the links between trade, environment and sustainable development. See, *e.g.*, **Charlie Arden-Clarke**, The GATT Report on Trade and Environment - A Critique by the World Wide Fund for Nature, Gland/Switzerland: WWF (1992), **Foundation for Environmental Law and Development (FIELD)**, The Multilateral Trade Organization: a Legal and Environmental Assessment, Gland/Switzerland: WWF Research Report, September 1992, and **Piritta Sorsa**, GATT and Environment, [1992] 1 *The World Economy* 115-133.

[165]**Michael Flitner**, Review of National Actions on Access to Genetic Resources and IPRs in Several Developing Countries, Gland/Switzerland: WWF (1995), affirms that during a meeting in June 1995 the CTE addressed for the first time the issues on IPRs and biodiversity, and that some delegations expressed worries in relation with the patentability of life forms.

framework, the CTE is already taking a step in the direction of clearing the doubts on the relationship between the provisions of the TRIPS Agreement and the principles created by the CBD.

Within the TRIPS Agreement there are some provisions that are likely to conflict with the principles of the CBD. It is worth noting that the TRIPS Agreement aims to provide a minimum basis for the harmonisation of national intellectual property laws which will lead to stronger protection of IPRs through a governmental authorisation to the right holder to exploit, under exclusive terms, the rights conferred to him. The CBD accepts that IPRs are part of technology transfer agreements and of the actions aiming at the exploitation of biological diversity. The CBD, however, is concerned primarily with technologies which may be developed to support the conservation and sustainable use of biological resources. Property rights systems shall not run counter to the objectives of the CBD.

Probably most of the provisions of the TRIPS Agreement are of interest in the present analysis. This Section shall, nevertheless, consider, in particular, two areas which may lead to some solutions or conflicts between the two international arrangements.

Article 27 of the TRIPS Agreement provides that Members of the WTO Agreement shall grant protection to all inventions, in all fields of technology, which are new, which involve an inventive step, and which are capable of industrial application[166]. Members of the WTO Agreement are nevertheless authorised to exclude from patent protection inventions which are against public order, morality,

[166]TRIPS Agreement, Art. 27 (1).

human, animal or plant life or health, or those inventions which are likely to cause serious prejudice to the environment[167].

As has been noted, the TRIPS Agreement considers the issues on environmental protection in very broad terms. How far this provision would authorise Members to take further action towards environmental protection, even by denying patent protection for some inventions on "environmental" grounds, is still a matter left for future interpretation.

Article 27 (3) (b) of the TRIPS Agreement also allows Members of the WTO Agreement to exclude from patent protection plants and animals and essentially biological processes for the production of plants and animals. Members are, nevertheless, required to protect micro-organisms, non-biological and microbiological processes and plant varieties[168].

In this regard, a few points must be made. Firstly, the wording of the TRIPS Agreement in relation with the protection of biotechnological products or processes is very vague in substance. It is not yet clear how this will be enforced by the dispute settlement mechanism of the WTO. It is also not clear if the developed economies will accept that developing countries' use, on grounds of "environmental" protection, of the exception provided by Article 27 (2), TRIPS Agreement, to refuse the granting of patent rights to biotechnological invention, even if the invention is a micro-organism, a non-biological or a microbiological process. In addition, it is not clear what the negotiators of the TRIPS Agreement meant by a non-biological process for the

---

[167] *Ibid.*, Art. 27 (2).

[168] Plant varieties are to be protected either by patents, by an effective *sui generis* system or by any combination thereof. *Cf.* Chapter 5, Part 2, Section 3, Sub-section 3.1, Paragraph 3.1.2, *supra*.

production of plants or animals. How a plant or animal could be produced by a process that is not partly or entirely a biological process is still to be determined and does not seem to be very feasible. It appears that the TRIPS negotiators intended to mean that a non-biological process is the one which does not use the reproductive system of the plant or animal in question to reproduce itself. The wording of Article 27 (3) (b), TRIPS Agreement, however, fails to suggest how Members of the WTO Agreement, particularly developing countries, would implement this provisional rule.

Secondly, the provisions of the TRIPS Agreement, although not expressly mentioned, are to a large degree based on the wording of the 1978 revision of the UPOV Convention. Developing countries may benefit more from the 1978 version of the UPOV Convention which accepts a rather flexible approach to protection. While the 1991 version of the Convention states in Article 2 that "[e]ach Contracting Party shall grant and protect breeders' rights", the same provision in the 1978 text accepts that Contracting Parties may recognise the right of a breeder either by the plant breeders' rights system, by patents, or by a combination of both systems[169].

Finally, it is important to remark that it was decided that Article 27 (3) (b) should be reviewed in four years after the date of entry into force of the WTO Agreement. In the future, it is possible that issues concerning the "biodiversity-related aspects of intellectual property rights" will become more important within the context of the TRIPS Agreement and perhaps it will be the task of the CTE to enhance this importance. It is definitely necessary that further consideration is given in this regard

---

[169] According with **James Cameron & Zen Makuch**, The UN Biodiversity Convention and the WTO TRIPS Agreement: Recommendations to Avoid Conflict and Promote Sustainable Development, Gland/Switzerland: WWF (1995), p. 12, to accede to the 1978 version of the UPOV Convention States should had done so by the end of 1995.

by Members of the WTO Agreement, to avoid future conflicts between the principles and norms of the CBD and those of the TRIPS Agreement, and to promote sustainable development of biological resources.

In addition to the provisions on patent protection, the TRIPS Agreement governs the protection of undisclosed information which, in my opinion, may be used as a legal tool to protect traditional knowledge of local and indigenous communities. Despite juridical and doctrinal doubts whether trade secrets are intangible property or "subjective rights" and, therefore, if they are protectable under the current system of intellectual property laws[170], Article 39 (2), TRIPS Agreement, rules that Members of the WTO Agreement shall give the possibility to anyone (either natural or legal person) "... of preventing information lawfully within their control from being disclosed to, acquired by, or used by other without their [owners'] consent in a manner contrary to honest commercial practices ...". The conditions to be fulfilled before protection may be granted are the following: (a) the existence of information which is secret; (b) the information has commercial value because it is secret; and (c) all reasonable steps have been taken to keep such information secret. In the absence of any provision regulating the term of protection of undisclosed information, it is possible to conclude that the TRIPS Agreement grants protection for valuable undisclosed information for an unlimited period, if the conditions above-listed are met.

This seems to be of great importance in protecting knowledge that has been developed and which has endured throughout the centuries. However, some substantive requirements of the law apparently cannot be met by indigenous societies.

---

[170] *Cf.* Chapter 2, note 169, *supra*.

In the case of a patent, for instance, the conditions of novelty and inventive activity, as traditionally established in connection with the prior art concept, are unlikely to be fulfilled by indigenous knowledge and practices. Also, in relation to trade secrets it is possible to argue that protection of information as a secret is no longer available in a legal sense in so far as indigenous communities and individuals have been exchanging information about their environment on a large scale. Case law may broaden the interpretation of legal concepts and recognise, within the traditional intellectual property system, indigenous intangible rights.

CONCLUSION

The present Chapter has described the "modern" approach towards the protection of IPRs as in connection with biodiversity conservation. Probably one of the greatest challenges that the international community is facing at the turn of the century is to determine a balance between the common interest of biodiversity conservation and the private interest related to the activities of industries which use biodiversity resources as a main source of materials. This balance is not easily reached and the legal mechanisms agreed so far do not cover the subject exhaustively. The international community, however, has agreed upon very important principles which have undoubtedly influenced the debate about the sustainable use and conservation of biodiversity.

It is obvious, from the present discussion, that the CBD did not attempt to set up very strict and detailed norms. The text of the CBD must be seen rather as a list of binding principles to guide national legislative initiatives. These principles aim at the

conservation of biological diversity, the sustainable use of its components and the fair and equitable share of the benefits arising from the utilisation of genetic resources. The goal of fair and equitable share of the use and exploitation of genetic resources is, for the purposes of the present analysis, the most important one, in so far as the CBD recognises the intrinsic economic, commercial and scientific value of biodiversity resources, providing thus a link between international and national trade and biodiversity conservation.

I tend to think that the established international economic order should be re-thought. The present system is unfair. Of course, there will always be the rich and the poor. Recently, however, the gap has grown too wide and the situation is becoming unbearable. In 1992, the UNCED appears to have concluded that the primary sources of the destruction of the planet's environment are firstly, the industries of the First World, secondly, the poverty of the Third World and, thirdly, the deforestation which is occurring in the impoverished South. Not surprisingly, the discussions have dealt primarily with the last of these sources.

The valuable biological resources held by the poor countries might be used as an essential bargaining tool to restrict the practices of the rich countries. Moreover, these resources can be used to further the economic and technological development of the poor countries. If the trading world continues to use the traditional concepts of the established international economic order which maintain the current system of international power, the planet's environment will be put in jeopardy. Thus, although it is claimed that the protection of the environment is the most important priority, this would not in fact be the case. Trade must take into account the priorities of the poor

as well as the investments and needs of the rich. Profits must be used to move towards a more just, equitable and stable society with a higher shared welfare. The implementation of the provisions of the CBD must take into account not only practical, economical and commercial aspects, but also the social and technological needs of developing countries and the ethical and moral rights of indigenous and local communities.

It is necessary, therefore, to give emphasis to the fact that the implementation of the concept of sovereign rights over genetic resources, in this context, is an strategic issue. As has been mentioned, national legislation have exclusive jurisdiction for regulating access to genetic resources and this includes the discretion to determine national proprietorship over biological. The mere affirmation of the sovereign rights principle, however, is not enough. Technology transfer, as recognised by several provisions of the CBD, is an essential mechanism to enhance the protection and the sustainable use of the biodiversity of the planet. Thus the application of the sovereign rights principle must be looked at in broad terms. National legislation shall draw up guidelines which are sustainable for the purpose of biodiversity conservation and that accept the importance of modern technology, as well as of the traditional practices of local and indigenous communities.

The evolution of the principles and substantive law for the conversation of biological diversity - including access to genetic resources, transfer of technology and the protection of indigenous rights - is not really a matter of controversy. National legislative measures seem necessary, but they must go beyond environmental policy considerations. National science and technology and industrial policies must take into

account measures necessary to protect the environment in its broadest sense. Access to genetic resources presents a unique possibility of bargaining against the capitalist world. If biological resources will be exploited - and they will be by indigenous communities, national governments or foreign undertakings - regulatory measures are indeed necessary.

Legislative initiatives should be welcomed, but they are not necessarily the easiest - or the shortest - way to achieve the goals established by the CBD. Edesio Fernandes[171], discussing the implementation of environmental international principles into the Brazilian legal framework, pointed out that,

> As a matter of fact, it is not a case of enacting more laws: on the contrary, even if it is true that some laws need to be improved and updated, the point is to guarantee the proper use of the potential offered by the existing legislation.

And that is the specific circumstance that has been discussed in this Chapter. While there is no adequate legislation to apply and enforce intangible indigenous rights and to regulate access to genetic resources, this matter could be analysed by national administrative and judicial authorities, bringing together existing ordinary and constitutional laws, international rules which are already part of the national legal framework and forthcoming principles arising from the legislative debate. National authorities are bound by the instruments mentioned above and will have to decide upon it when analysing the conditions of an intellectual property application (national industrial property offices) and when judging a particular dispute concerning either

---

[171] **Edesio Fernandes**, Law, Politics and Environmental Protection in Brazil, [1992] 1 *Journal of Environmental Law* 41-55, at p. 43.

access to genetic resources or indigenous rights (national courts). Juridical understanding of the matter will be then construed, and further interpretative approach to forthcoming legislation could be enriched.

The foregoing introductory remarks are necessary to present further conclusions arising from the issues analysed in this Chapter. As has been mentioned, compared with the government itself the Brazilian Parliament has shown a higher degree of legislative initiative in relation with biodiversity conservation matters. The government has failed to address the subject in a legislative form which has led to a lack of co-ordinated actions aiming at implementation of the CBD. This may create an inappropriate interpretation of the principles established by the CBD and by the Brazilian Federal Constitution. A clear example of this situation is that a legislative Bill, originating in the Chamber of Deputies (PL 2057/91), discusses the issues on the protection of traditional knowledge and practices of indigenous communities while another legislative Bill, originating in the Federal Senate (PLS 306/95), proposes norms to regulate access to genetic resources, dealing also with the issues on the protection of traditional knowledge and practices. Government and both Houses of Parliament should work in harmony to draw up the necessary legal measures to implement the principles of biodiversity conservation.

PLS 306/95, in particular, should be subject to some modifications. Firstly, Article 1 (III), PLS 306/96, determines that the country shall participate in the economic and social benefits arising from the exploitation of genetic resources, but it does not give emphasis to the participation in the scientific benefits as a necessary mechanism to determine national measures on the implementation of the fair and

equitable sharing of the benefits arising from the exploitation of national genetic resources. Scientific benefits are, indeed, a crucial principle to be included together with the economic, commercial and social benefits.

Moreover, the committee created by Article 5 of PLS 306/95 fails to include representatives of local and indigenous communities as part of the composition of such institutional mechanism created to monitor biodiversity conservation and sustainability. All biodiversity-related matters must consider an effective participation of indigenous and local communities in the decision-making process and during the development of strategies. This is a basic condition to consider an appropriate implementation of the CBD, in so far as research on genetic resources may have, directly or indirectly, influence in the lifestyle and cultural habits of local and indigenous populations.

PL 2057/91 and PLS 306/95 are in general terms compatible with the CBD. The CBD leaves a great degree of discretion to national legislation and does not discuss further how each of its principles should be interpreted by national law. It is important to consider, in this context, that national laws have great opportunities to develop further legal mechanisms which are compatible with their economical, social and technological needs. The implementation of the CBD by national legislation should be a result of a national debate with the participation of all parties involved, including Parliament, the scientific community, local and indigenous communities, non-governmental and governmental organisations, universities, as well as private and public undertakings. Within this discussion a national strategy towards biodiversity sustainability and conservation should be drawn up. Further suggestions on methods

for policies and institutional mechanisms in this context are provided in the final conclusion below.

In my opinion, there seems to be no further doubts in relation to the use and exploitation of genetic resources and of traditional knowledge and practices, within the context of an integrated area. This is more a matter of national jurisdiction. Obviously, once technology is protected by national law, and put into practice on national markets, the existing common rules for the MERCOSUL will apply to that technology, including the free movement of goods and competition law principles. In this context one problem that may occur is related to the recognition, by other States Parties, of similar legal rights protecting traditional knowledge and practices of local and indigenous communities. If other States Parties do not agree with the protection of indigenous and local communities' intangible properties, national administrative and juridical authorities will decide upon this particular situation taking into account either the common rules of patent protection for the MERCOSUL or the national legal framework. Interpretation of different frameworks, or even of a common legal structure, may lead to a diverse understanding of the subject. It is thus necessary to discuss the matter in more detail within the context of the MERCOSUL, although it appears that such an issue is particularly strategic only to Brazil.

CONCLUSION

It is necessary to bear in mind that the integrating project of the MERCOSUL is distinct from the process of integration in the European Union. The MERCOSUL has, at least in this stage, different goals if compared with those established by the EU. It does not appear that the MERCOSUL attempts to strengthen its political integration process as the EU has done. I am also not sure whether the MERCOSUL aims at having an integrated monetary policy put into practice by a common currency.

There are several circumstances that makes this distinction clear. Firstly, the European Union is predominantly an integrating project among developed nations with a high capacity for innovation and a long-established industrial structure. Though there are some countries that are not in this pattern of technological and/or industrial development, the wealthy nations of the region may subsidise the development of the others. Under some circumstances, and viewing it in general terms, this may also be the situation in the MERCOSUL. Argentina and Brazil, for instance, could finance the economic development of Paraguay and Uruguay, if their technological and industrial development levels were as competitive as those of the most advanced world trading nations, namely some Member States of the EU, Japan and the US. This, however, does not seem to be feasible in the short term.

A second difference which must be considered is that one of the supporting justification for the integration process of Europe has understood that peace, in Europe, would be assured by a more stable political system and by economic development, which would help the participating countries to recover from the Second World War. Of course, this is not to suggest that a system of economic integration necessarily leads to peace throughout the integrated system. It is simply to

state that to date it would seem that this has been the case for Europe. Moreover, it is hoped that the same will be true for the MERCOSUL, although the way in which peace is to be understood in the countries of the MERCOSUL differs from the European concept. Peace for the participating countries of the MERCOSUL is a much broader concept which includes the furtherance of their technological capabilities and the removal of their social inequalities.

A third circumstance is that the political goals of the two projects of approximation differ in substance. While the participating nations of the European Union work on, at least, the maintenance of their current condition concerning industrial and technological development and their position in the international market, the countries of Latin America have been struggling to advance their technological skills, with little, if any, help from developed nations and to increase their participation in the international market with manufactured goods rather than with raw materials or agricultural products. Technology transfer agreements in the new world order seems to be a mechanism used mainly by developed nations among themselves or by multinational corporations between their headquarters and their subsidiaries. Sometimes it seems that IPRs perform more efficiently the task established by the goals of the developed world, as technology owners.

It is also necessary, however, to recall that there are some similarities between the European integration project and the negotiations to establish the MERCOSUL. At some stage both integrating projects aim at economic and technological development and at providing better standards of living for their population. This is to be attained by the creation of an area where goods, persons, capital and services circulate without being restrained by any barriers and by the establishment of a

common trade policy which includes a common external tariff, the harmonisation of macro-economic policies and co-ordinated action in international negotiations. These are the principles that form the basis of both integrating projects, and their implementation is vital for the successful functioning of the integrated area. The methods used for implementing these goals are to be regulated on a regional basis, however, and will obviously differ in technical terms.

It is also apparent that the experience of the EU provides the MERCOSUL with many practical examples. Particularly in the field of patent protection, the EU practice is of great relevance for the setting up of common patent regulations in the MERCOSUL. There are, nevertheless, considerable differences between the two projects in their institutional and legislative framework, as well as in their level of economic and technological development. This should be considered by the integrating project of the MERCOSUL in the drafting of a common science and technology and industrial policy, as well as during the legislative initiatives aiming at the harmonisation of national legislation in the territory of the MERCOSUL. It is, however, necessary to remark that as the States Parties of the MERCOSUL are in a lower level of technological development, in comparison with the EU, the setting up of common regulations for patent protection and licensing should consider the possibility of having a growing technology regional market as a result of the technological co-operation efforts between the States Parties[1] and as a result of the

[1]Such co-operation in the field of science and technology is particularly suggested by the Preamble of the Treaty of Asuncion which says the following: "Convinced of the need to promote the scientific and technological development of the States Parties and to modernize their economies in order to expand the supply and improve the quality of available goods and services with a view to enchancing the living conditions of their populations".

trade liberalisation process itself. This will lead to the need of stronger and more detailed common rules regulating technology transfer and patent licensing agreements.

There are at least two major areas of analysis that should be taken into consideration for the setting up of policy guidelines in the context of the negotiating process of the MERCOSUL. I should like to place them under the following classification: legislative measures and institutional prospects. Both are closely related to each other and will be considered as such.

"Legislative measures" are undoubtedly necessary and have been considered in the light of current negotiations of the MERCOSUL by virtue of Article 1 of the Treaty of Asuncion that calls for, *inter alia*, the harmonisation of national legislation "... in the relevant areas in order to strengthen the integration process". One of these relevant areas is the harmonisation of regulations which deal with substantive patent law.

With regard to the harmonisation of national regulations on substantive patent law, Sub-group 7[2] has taken actions in this direction. The latest version of a text dealing with patent regulation mechanisms is nevertheless superficial and seems to avoid the most controversial issues. Some consideration is particularly necessary in the following areas: pharmaceutical products and processes, biotechnology, plant varieties, free movement of goods and competition law principles, and "biodiversity-related aspects of intellectual property rights".[3]

---

[2]*Cf.* Chapter 1, Section 2, Sub-section 2.2, Paragraph 2.2.2, *supra*.

[3]For the discussion about pharmaceuticals, biotechnology and plant varieties, see Chapter 4, Section 3, Sub-section 3.3, and Chapter 5, Part 2, *supra*. For an analysis of the establishment of common rules on free movement of goods and competition law principles, see Chapters 3 and 6, *supra*. For an analysis of the "biodiversity-related aspects of intellectual property rights", see Chapter 7, *supra*.

1. The protection of pharmaceuticals appears to be of no further controversy. This is an international trend, imposed by developed nations, that seems unavoidable *vis-a-vis* the international commitments of the participating countries of the MERCOSUL. The TRIPS Agreement has defined the scope of protection and States Parties of the MERCOSUL will have to comply with it.

Although legal protection for both products and processes is agreed - or will be as a matter of law - there are several other questions that should be considered. The fact that patent protection will be available is not enough in this regard. In addition to the protection of pharmaceutical products and processes, a common policy has to focus on the development of a pharmaceutical industry in the region with the technological capacity of, at least, producing generic drugs. Medicine is, and has always been, an strategic concern of all nations.

Alongside policy in this area, another concern emerges. There are in the territory of Brazil several biodiversity components that may be very valuable to the development of new drugs. Legal mechanisms are necessary to enable the participation of the country provider of such resources in the research that will lead to the development of new medical products. Such a policy has to consider not only the just and equitable sharing of the economic benefits that may arise from the commercialisation of a new product but also the participation of the provider country in the research itself. This would help the country in which genetic resources are present to develop human resources capabilities which may lead to the development of their own technologies in the medium or long term. Indeed, a science and technology policy has to consider broadly the aspects of human resources, access to and transfer of technologies and the sharing of economic and scientific benefits.

2. In connection with the protection of biotechnology, it is clear that neither the international community nor the participating countries of the MERCOSUL have reached a common position yet. On the international level, for instance, the TRIPS Agreement shows that a common position could be reached during future negotiations. Brazilian legislation, on the other hand, seems to have taken a reasonably serious approach towards the subject by providing for the granting of protection for biotechnological inventions in definite terms. But how is the problem going to be dealt with in the context of a Common Market? The negotiations of the MERCOSUL have firstly to decide whether protection is going to be granted or not. If it is to be granted, they will have to decide under which terms such protection will be made available. Are animal and plant varieties going to be included in the scope of protection? How are micro-organisms and transgenic varieties going to be defined in this context? The most reasonable approach in this area is to wait for further definition in the international discussion to set up more pragmatic legal mechanisms for protecting biotechnological inventions. In the meantime, the negotiations of the MERCOSUL could reach an agreement to set up a provisional type of protection for biotechnological inventions. They may provide protection for micro-organisms and transgenic varieties of plants and animals in a provisional basis, making clear that this type of protection would be granted for a specific period of time and that modifications would be forthcoming. Once the negotiations in the international and regional levels are more well defined, further discussion could take place and a more detailed legal mechanisms could be created.

Additionally, when one talks about the protection of biotechnological products there are several other issues that have to be considered. Biosafety measures will have

to be created on a regional basis to regulate the storage, transportation and marketing of products which are the result of biotechnological research. Provisions contained only in national laws will certainly create conflicts with the other national legal frameworks of the participating countries of the MERCOSUL. The harmonisation of national laws on the protection of biotechnological inventions will have to consider the aspects of biosafety as a necessary mechanism to complement the system of biotechnology protection as a whole.

3. With regard to the protection of plant varieties the situation is the following. Argentina and Uruguay are already Contracting Parties of the UPOV Convention and have national measures to protect plant varieties under the breeders' rights system. Brazil is apparently negotiating its accession to the UPOV Convention, but a national legal mechanism to regulate plant varieties protection is unlikely to be established soon. In addition, the TRIPS Agreement, although provisionally, permits that Members of the WTO Agreement grant protection to plant varieties either by patents, by the UPOV system or by a combination of both mechanisms. If each State Party of the MERCOSUL grants protection for plant varieties under different approaches, it seems that conflicts will arise from such a non-harmonised framework. If all countries are likely to become Contracting Parties to the UPOV Convention, it is possible to suggest that the negotiations of the MERCOSUL should consider the UPOV system to implement a common system for the protection of plant varieties, agreeing, thus, upon a common system of protection for the entire area. That seems to

be a quite reasonable approach to the problem. Note, for example, the solution found by the EC Plant Variety Regulation[4].

4. In relation with the harmonisation of national laws implementing the principles that goods shall circulate freely and that a healthy competitive market shall prevail in the context of the MERCOSUL, a few other considerations shall be made. It is first necessary to recognise that the appropriate implementation of both principles is vital for the successful and full establishment of the integration process itself. They are also totally inter-related. The implementation of one of these principles will have to consider the other in a complementary manner.

With regard to the harmonisation of the understanding on the free movement of goods principle, I should like to suggest in the first place that a common understanding of the application of this principle should be created. As has been seen, the Treaty of Asuncion only determined that one of the principles for the establishment of a Common Market was that goods shall circulate freely. No other guidance was provided in this regard by the Treaty of Asuncion. It is thus necessary to determine, first, what the principle is and how it should be viewed within the context of the integration process. Once general rules are established in this regard, secondary regulations, dealing with particular aspects of the integration process, such as the exercise of IPRs in the integrated area, must consider the specific characteristics of the application of the principle of free movement of goods in such particular context.

---

[4]Discussed in more detail in Chapter 4, Section 3, Sub-section 3.3, Paragraph 3.3.3, *supra*.

The regulation of competition in the integrated area is also of paramount importance for the successful implementation of the Common Market. A common mechanism, as has been seen in Chapter 6, Section 2, Sub-section 2.3, *supra*, is in the process of being established. The common approach to the subject has suggested provisions on unfair competition which appear sufficient and clear. There are, nevertheless, particular characteristics related with the exercise of IPRs in the integrated area. Licensing agreements, for instance, require very detailed regulations which consider the particular properties of licensing practices. The way that technology, know-how and patents are to be transferred and "commercialised" in the MERCOSUL has to be harmonised in order to ensure that the competitive market prevails and that consumers are benefited by such practices.

5. The issues relating to the implementation of the Convention on Biological Diversity are also complex and broad. There is a need to determine how the integrated area of the MERCOSUL will deal with these modern aspects of IPRs. The implementation of common provisions in this field, however, must be looked at from a more pragmatic viewpoint. Environmental considerations of the policy-making process has to be part of the whole system of science and technology and industrial policies. An IPRs framework must, therefore, consider the particular characteristics of access to genetic resources, technology transfer agreements, biotechnology and the protection of traditional knowledge and practices. All these areas, as has been described in Chapter 7, *supra*, are completely inter-connected and they must be harmonised as such.

To consider the harmonisation of the "biodiversity-related aspects of intellectual property rights" one must firstly consider some policy measures which are

part of the overall context. A system must be created to determine a decentralised approach towards biodiversity conservation and sustainable use. More decision-making powers shall be given to local and indigenous communities, while financial and legal assistance shall be provided by national governments.

Complementarily, a more effective interaction between all "stakeholders" should be encouraged by a common regulation aiming at monitoring and preserving biodiversity. The concept of the expression "stakeholders" in this context has to be broadly defined by a common legislation as well. "Stakeholders" are local and indigenous communities, public interest, scientific and academic communities, private sector and governmental and non-governmental agencies. This is indeed a broad definition of the concept. The difficulty presented here is not related to the definition of the concept itself, but with the establishment of the role of each "stakeholder" in the process of biodiversity conservation. This role has to be determined by policy guidelines on environmental conservation, considering, obviously, science and technology and industrial policies as part of the process in its entirety. Legal instruments will only determine the degree of application of the guidelines provided by policy measures.

Policy measures must also consider the development of administrative and institutional guidelines. At this stage of the establishment of mechanisms for biodiversity conservation, it seems that the functions of some administrative organs are overlapping other governmental and non-governmental organs' functions. This overlap does not lead only to unnecessary repetition of work, but also to gaps which are not fulfilled by either organs.

A common policy for the MERCOSUL in the area of biodiversity prospecting must be considered as a development strategy. The MERCOSUL may gain economic and technological capacity from the establishment of common policies on access to genetic resources in its broadest sense. Such a policy must foster the interaction between legal protection in the field of pharmaceuticals, biotechnology and plant varieties with national strategies on access to genetic resources. Though sovereign rights over genetic resources regulation rests with national legal instruments, it is possible to develop common strategies to implement the application of national norms. These strategies must include the establishment of a unified understanding on the protection of traditional practices and knowledge, biosafety measures and on the recognition of national regulations dealing with procedural and substantive aspects of access to genetic resources. These strategies must additionally consider mechanisms which encourage technology transfer instruments as a means of developing further the national and regional capacities in the field of biotechnology, agriculture, medicines, etc. Strategies, within the context of the MERCOSUL, should be viewed in regional terms and should consider the technological and economic development of the region as going beyond national interests. At the end of the day, if States Parties of the MERCOSUL co-ordinate their actions on institutional and legislative developments in the field of biodiversity the mutual gain would benefit all.

Moreover, there are key elements which should be also considered within the context of the MERCOSUL to determine the level of technology transfer from developed countries to the region. These elements should be used as the basis of national or regional regulations in this field: (a) training and access to information; (b) development of technological capacity in biodiversity prospecting through technology

transfer agreements; (c) development of regional negotiating power in biodiversity prospecting, which would consider the balance between environmental, economic and scientific benefits; (d) encouragement of access to technology which is environmentally friendly through co-ordinated strategies on "North/South" relations; and (e) encouragement of innovations in public or private national or regional industries, by supporting their participation in the process of biodiversity prospecting.

On the international level, it is possible to draw up further actions towards international recognition and acceptance of the sovereign rights principle over genetic resources and of the value of traditional practices and knowledge. Co-ordination in the actions of the States Parties of the MERCOSUL are necessary to work towards the inclusion of multilateral acceptance of biodiversity principles. Within the WTO system, particularly, co-ordinated actions should move towards the inclusion of strong provisions on the recognition of the sovereignty of national regulations on access to genetic resources. The forthcoming revision of Article 27 (3) (b) of the TRIPS Agreement should therefore contain provisions which guarantee the multilateral acceptance of the need for the creation of a *sui generis* system for the protection of traditional knowledge and practices of local and indigenous communities as well. Co-ordinated actions in this manner could be also negotiated under the auspices of the WIPO.

Under the heading "institutional prospects", other considerations are required. The current institutional framework of the MERCOSUL seems superficial, leaving several gaps for future agreement. This is probably an outcome of the nature of the integration process itself, which considers the MERCOSUL rather as a negotiation process than as an integrated area. The final goals of the MERCOSUL have not been

defined so far, and a more precise institutional framework will be probably drafted in more detail once the Common Market is fully established. I propose to address the subject on three levels: political, administrative and juridical.

1. Strictly speaking the Council of the Common Market is the only political institution of the MERCOSUL. Very limited in essence, this political body is composed of the Ministers of Foreign Affairs and the Ministers of Economy of the States Parties. Although the Ministers of the States Parties will be advised by other sectors of national economies, by other institutions of the MERCOSUL and by other intergovernmental bodies, in order to formulate policies and promote measures for the establishment of the Common Market, this is still limited as a negotiating process.

Probably the most traditional and effective way for the setting up of an institutional framework which represents the population of the countries involved is the creation of a regional Parliament. Though the national Parliaments are represented in the MERCOSUL by the Joint Parliamentary Commission (JPC), the latter's task is very much limited to speeding up the process of implementation of the decisions taken by the organs of the MERCOSUL and to assisting with the harmonisation of legislation. Indirectly, the JPC has a very effective legislative power because it will function as an intermediate organ between national Parliaments themselves and between the institutional framework of the MERCOSUL and the Parliaments of the States Parties. Every national Parliament, however, with its own ideological and political tendencies, may harmonise common measures for the MERCOSUL in different ways, taking into account the political and cultural distinctions between the participating countries in connection with the level of industrial and technological

development of each and the national political characteristics, which includes the degree of support that the President of each State Party has in his own Parliament.

Probably the wills of the national economic and social sectors of each State Party will be institutionally expressed by the Economic-Social Consultative Forum (ESCF). But, as underlined by its own name, the Economic-Social Consultative Forum will have only consultative functions. No decision-making power was given to either the ESCF or the JPC.

2. On the administrative level, and particularly related to patent protection mechanisms, the MERCOSUL lacks a regional institutional arrangement to deal with administrative procedures for granting and judging patent rights. Thus, even if a common agreement on the unification of national patent laws is reached, the administrative application of the common principles will vary between national patent offices. Joint efforts could make patent granting procedures more efficient by centralising it into one single body with a highly capable structure of human resources with the required technical skills to assess patent applications in the several fields of protection. This institutional mechanism could be designed to work together with national patent offices or, even, to operate as a second instance body which would have the main function of harmonising the technical assessment of national patent offices. Such a common organ could also provide preliminary rulings on questions raised by national patent offices.

3. Another difficulty that may arise during the implementation of the common principles of the MERCOSUL is the lack of a common juridical structure designed to harmonise national court rulings. Though there is a MERCOSUL Trade Commission which will consider complaints originated by States Parties or by individuals, relating

to the implementation and application of the rules created by the Treaty of Asuncion, its Protocols and by the Decisions taken by the organs of the MERCOSUL, the task of the MERCOSUL Trade Commission, and of the *Ad hoc* Arbitration Tribunal, under the Protocol of Brasilia, will be limited. Their decisions are directly applicable in the national legal framework, but are limited to the specific dispute in which it was called upon to decide. With a predominant cultural and social diversity, national courts in different regions of the territory of the MERCOSUL may very likely decide upon similar issues in different ways. As a consequence, discussion on, for example, the application of competition rules and the implementation of the free movement of goods principle may suffer strongly from the lack of a harmonised juridical approach towards the subject, particularly in the case of disputes involving patent rights.

All that was said above must be considered for the setting up of a common policy for the MERCOSUL. In addition, there are other structural changes that may have to take place to enable proposals of guidelines for science and technology, environmental and industrial policies.

Taking all that into account, I would like to say that there are foreseeable solutions in the medium term. It is also possible to make assumptions related to the role of the harmonisation of national laws on patent protection in scientific and technological development for the region, if there is a co-ordinated policy for science and technology which considers the setting up of environmental and industrial policies as inter-connected concepts.

The following suggestions of guidelines for policy-making are to be considered within a broad concept which includes the harmonisation of legislation and the strengthening of institutional mechanisms:

(a) Legislation of the participating countries has to be harmonised - or unified by the mechanism of inter-State Conventions - in detail, taking account of the most controversial and complex issues. If a common position cannot be reached in the negotiation level, general principles must be established. The harmonisation, or unification, of legislation has to consider the following aspects in detail: the scope of application of protection of pharmaceutical products and processes; the system which will be used for the protection of plant varieties; common rules for regulating competition and for implementing the free movement of goods principle within the integrated territory; and common rules to regulate and control access to genetic resources, including regional acceptance of a *sui generis* system to protect traditional knowledge of local and indigenous communities.

(b) The establishment of common administrative institutions to approach patent granting procedures on a harmonised basis. This could be attained by the creation of a common organ to work together with national patent offices or to give preliminary rulings on administrative and technical questions raised by national patent offices

(c) The creation of a supranational juridical body the decisions of which would be directly applicable before the national courts of the States Parties. This regional institution would in addition provide legal and juridical advice on questions brought before it by national courts, as with the European Court of Justice under Article 177 of the EC Treaty.

(d) The setting up of a legislative body, democratically elected by the population of the States Parties, with more legislative functions than those

of the Council of the Common Market. The Council of the Common Market, together with the Common Market Group and the MERCOSUL Trade Commission would have the power of initiative to propose regulatory mechanisms, but final decisions would be left to a Regional Parliament. For the implementation of this proposal, methods of transfer of sovereign rights to supranational bodies would have to be considered.

(e) The creation of a Regional Council of Science and Technology with the functions of planning and deciding upon the setting up of guidelines for regional science and technology policy. This body would be funded by contributions from national governments and would be comprised of representatives of governments, industries, workers, academic institutions and national scientific organisations. This fund would finance research in all areas deemed strategic and/or necessary for economic, technological, scientific, educational and social development, through co-operation agreements with third parties and by the granting of scholarships to researchers and students. The private sector would be strongly encouraged to support specific projects of interest in their particular field of activity. The private sector would also be encouraged to work together with universities in funding research projects, co-operating with technical information, and supporting research and development.

(f) Science and Technology policy guidelines have to define clearly the goals in the short, medium and long term, as well as the balance of investments

in basic, applied and development research[5]. It must also optimise the use and establishment of human resources and not address research and development directly as a means of competing with the developed nations. The drafting of a common policy on science and technology should be regarded as part of a common strategy which would take into account industrial and environmental policies as an integral part of the overall concept.

(g) There should be support for the setting up of co-operation agreements with private entities, academic institutions or governments from developed and developing countries. These co-operation agreements on, for instance, access to genetic resources, could include the necessary regulation of the sharing of the economic and scientific benefits arising from research using genetic resources; the setting up of training activities and development of human resources from the country which is the provider of the genetic material; the recognition of the rights of local and indigenous communities; and biosafety measures. Co-operation agreements in the field of genetic resources could be used as a mechanism to develop further the technological capabilities of the States Parties in this area. Research should be carried out preferably in the host country, but such measure should be flexible enough to accept the need of research being carried out in the

[5]**Hiroshi Inose & Akira Tezuka**, A System Approach to Japanese Basic Research, paper presented to the Japan-German Science Policy Seminar, Tokyo, May 1984, p. 1, provides the following definition: "Basic research is defined as the research undertaken for the advancement of scientific knowledge, where a specific practical application is not directly aimed at. Applied research is defined as the research undertaken for the advancement of scientific knowledge, with a specific practical application in view. And development research is defined as the use of results available from basic

international institution in question. The scope of transfer of or access to technology should be broadly defined and include various technological elements such as patents, know-how and continuous technical assistance for equipment which are part of the technology transfer.

(h) The creation of guidelines to provide a regional balance within the MERCOSUL and within the States Parties of development of centres with technological capabilities. This could be done by encouraging the private sectors to work in co-operation with universities of regions which have not been given sufficient financial and human resources to develop their own science and technology capabilities. This should consider, as far as possible, the development of technologies which could directly benefit the population of these regions.

---

and applied researches, and actual experiences, directed to the introduction of new materials, equipments, systems, and processes, or the improvement of such existing ones, ...".

BIBLIOGRAPHY

Articles, Chapters from Edited Books and Other Papers

ADAMS, John

Supplementary Protection Certificates: the Challenge to EC Regulation 1768/92, *European Intellectual Property Review*, N. 8, 1994, pp. 323-326

ALMEIDA, Paulo Roberto de

Cronologia da Integração Latino-Americana no Contexto do Sistema Econômico Internacional, *Boletim de Integração Latino-Americana*, N. 16, 1995
(*http://www.mre.gov.br/getec/webgetec/bila/16/4notas/1nota.html*)

AMORIM, Celso Luiz Nunes

O Mercado Comum do Sul e o Contexto Hemisférico, *Boletim de Diplomacia Econômica*, N. 7, April/May 1991, pp. 3-8

ARDEN-CLARKE, Charlie

The GATT Report on Trade and Environment - A Critique by the World Wide Fund for Nature, Gland/Switzerland: WWF Position Paper (1992)

ARNOLD, Tom & Ed Goldstein

Compulsory Licensing: The "Uncentive" for Invention, *Patent Law Review*, N. 7, p. 113

BARDEHLE, Heinz

WIPO Patent Harmonization: a Time for Compromise, *World Intellectual Property Report*, Vol. 5, N. 4, April 1991, pp. 95-99

BARENTS, R.

New Developments in Measures Having Equivalent Effect, *Common Market Law Review*, Vol. 18, 1981, pp. 271-308

BEIER, Friedrich-Karl

The European Patent System, *Vanderbilt Journal of Transnational Law*, Vol. 14, 1981, pp. 1-16

BERGEL, Salvador Dario

Desarrollo Sustentable y Medio Ambiente: La Perspectiva Latinoamericana, *Revista del Derecho Industrial*, Vol. 41, 1992, pp. 303-343

BETHEM, J.B. van

The European Patent System, Today and in the Future, *European Intellectual Property Review*, N. 7, 1984, pp. 182-188

BETON, J.L.

Future Prospects-Harmonisation of National Patent Laws, *European Intellectual Property Review*, January 1979, pp. 13-19

BLEJER, Mario I.

Economic Integration: An Analytical Overview, in **Inter-American Development Bank & Institute for Latin American Integration**, Economic and Social Progress in Latin America - Economic Integration (1984 Report), Washington, DC: Inter-American Development Bank (1984), pp. 5-34.

BOWEN, R. & A. Parry

European Patent Convention: The First Convention, *Common Market Law Review*, Vol. 11, 1974, pp. 105-113

BRADLEY, Clive

The Role of GATT in Intellectual Property, *Copyright bulletin*, N. 3, 1991, pp. 11-15

BRUSH, Stephen

Indigenous Knowledge of Biological Resources and Intellectual Property Rights: the Role of Anthropology, *American Anthropologist*, 1993, pp. 653-686

BURSHTEIN, Sheldon

Confidential Information is not Property in Canada, *Industrial Property*, N. 11, 1988, pp. 55-58

BYRNE, Noel

Patent Tie-in Arrangements and Article 85, *European Intellectual Property Review*, 1980, pp. 141-148

CAMERON, James & Zen Makuch

The UN Biodiversity Convention and the WTO TRIPS Agreement: Recommendations to Avoid Conflict and Promote Sustainable Development, Gland/Switzerland: WWF (1995)

CARMINATI, Antonella

A Aplicação do TRIPS na Ordem Jurídica Interna, *Revista da ABPI*, N. 17, 1995, pp. 13-17

CERANTOLA, Willian Antonio

Estratégias Tecnológicas das Empresas de Biotecnologia no Brasil, *Revista de Administração*, Vol. 27, N. 2, 1992, pp. 5-14

CHALLÚ, Pablo

The Consequences of Pharmaceutical Product Patenting, *World Competition*, N. 2, 1991, pp. 65-126

CHARTERED INSTITUTE OF PATENT AGENTS, THE

Briefing Paper: The European Commission Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, *mimeo*, August 1992

CLOSE, George

Harmonisation of Laws: Use or Abuse of the Powers under the EEC Treaty?, *European Law Review*, Vol. 3, 1978, pp. 461-481

CORNISH, William

The Essential Criteria for Patentability of European Inventions: Novelty and Inventive Step, *International Review of Industrial Property and Copyright Law*, N. 6, 1983, pp. 765-775

CORREA, Carlos

The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection, *European Intellectual Property Review*, N. 8, 1994, pp. 327-335

COTTIER, Thomas

Intellectual Property in International Trade Law and Policy: the GATT Connection, *Aussenwirtschaft*, 47 Jahrgang (1992), 79-105

COTTIER, Thomas

The Prospects for Intellectual Property in GATT, *Common Market Law Review*, Vol. 28, 1991, pp. 383-414

CURRAL, Julian

Some Aspects of the Relation Between Articles 30-36 and Article 100 of the EEC Treaty, with a Closer Look at Optional Harmonisation, *Yearbook of European Law*, Vol. 4, 1984, pp. 169-206

DA COSTA E SILVA, Eugênio

Brasil-Estados Unidos e a Propriedade Industrial, *Correio Braziliense*, 4 June 1995, p. 7

DASHWOOD, Alan

The Harmonisation Process, in **Carol C. Twitchett** (ed.), Harmonisation in the EEC, London: The MacMillan Press Ltd. (1981)

DHANJEE, Rajan & Laurence Boisson de Chazournes
Trade Related Aspects of Intellectual Property Rights (TRIPS): Objectives, Approaches and Basic Principles of the GATT and of Intellectual Property Conventions, *Journal of World Trade*, N. 5, pp. 5-15

EASSON, A.J.
EEC Directives for the Harmonisation of Laws: Problems of Validity, Implementation and Legal Effects, *Yearbook of European Law*, Vol. 1, 1981, pp. 1-44

EMPEL, M. van
European Patent Conventions, *Common Market Law Review*, Vol. 9, 1972, pp. 13-34

EMPEL, M. van
European Patent Conventions: the First Convention in the Semi-Finals, *Common Market Law Review*, Vol. 9, 1972, pp. 456-465

FERNANDES, Edesio
Law, Politics and Environmental Protection in Brazil, *Journal of Environmental Law*, Vol. 4, N. 1, 1992, pp. 41-55

FERRY, John
Patent Agreements: No-challenge Clauses, *European Intellectual Property Review*, N. 4, 1989, pp. 138-139

FLITNER, Michael
Review of National Actions on Access to Genetic Resources and IPRs in Several Developing Countries, Gland/Switzerland: WWF (1995)

FOLHA DE SÃO PAULO
Acordo da Venezuela com o MERCOSUL Tem Apoio do Brasil, *Folha de São Paulo*, 21 May 1996

FOLHA DE SÃO PAULO
Chile Assina Acordo com o MERCOSUL, *Folha de São Paulo*, 23 March 1996

FOLHA DE SÃO PAULO
Chile Entra para o MERCOSUL, *Folha de São Paulo*, 26 March 1996

FOREIGN & COMMONWEALTH OFFICE,
Latin America's Regional Integration Process
(*http://www.fco.gov.uk/reference/briefs/latinamerica.html*)

FOUNDATION FOR ENVIRONMENTAL LAW AND DEVELOPMENT
The Multilateral Trade Organization: a Legal and Environmental Assessment, Gland/Switzerland: WWF Research Report, (September 1992)

FRIDEN, G.
Recent Developments in EEC Intellectual Property Law: the Distinction Between Existence and Exercise Revisited, *Common Market Law Review*, Vol. 26, 1989, pp. 193-218

FROSCHMAIER, Franz
Some Aspects of the Draft Convention Relating to a European Patent Law, *International Comparative Law Quarterly*, N. 12, 1963, pp. 886-897

FURTADO, Lucas
Patenteamento de Microorganismos, Brasília: Assessoria Legislativa da Câmara dos Deputados, *mimeo*, 1993

GALL, Günter
Legislative and Judicial Power in Europe - How Far is Harmonisation of Patent Law and Practice Possible and Desirable?, *European Intellectual Property Review*, N. 5, 1988, pp. 138-142

GAUMONT, Robert
Patentability and Patent Scope of Pharmaceuticals Inventions, *International Review of Industrial Property and Copyright Law*, N. 13, 1982, pp. 431-458

GLADWELL, David
The Exhaustion of Intellectual Property Rights, *European Intellectual Property Review*, N. 12, 1986, pp. 366-370

GONTIJO, Cícero, Fernando Antonio Lyrio Silva, Francisco Eugênio Machado Arcanjo & Ronaldo Bayma Archer da Silva Contribuição à Compreensão do PLC 115, de 1993, Brasília: Assessoria Legislativa do Senado Federal, *mimeo*, 22 September 1993

GORDON, Maxwell
Licensing's Impact in Pharmaceuticals, *les Nouvelles*, Vol. XXVI, N. 4, 1991, pp. 160-165

GORMLEY, Laurence
Recent Cases on Articles 30-36 EEC, *European Law Review*, N. 10, 1985, pp. 431-457

GREEN, Daniel

European Companies Take on the World, *Financial Times*, 20 January 1995, FT500, p. 39

HAARDT, W.L.

Infringement Procedure According to the Draft Convention Relating to a European Patent Law, *Common Market Law Review*, Vol. 1, 1963-1964, pp. 202-209

HEITZ, André

The History of Plant Variety Protection, in **UPOV**, The First Twenty-Five Years of the International Convention for the Protection of New Varieties of Plants, Geneva: UPOV (1987), pp. 53-96

HOFFMANN, Dieter & Orlagh O'Farrel

The 'Open Exclusive Licence' - Scope and Consequences, *European Intellectual Property Review*, N. 4, 1984, pp. 104-110

HORLICK, Gary

Dispute Resolution Mechanisms - Will the United States Play by the Rules?, *Journal of World Trade*, Vol. 29, N. 2, 1995, pp. 163-172

ISONE, Horishi & Akira Tezuka

A System Approach to Japanese Basic Research, paper presented at the Japan-German Science Policy Seminar, Tokyo, May 1984

JORNAL DO BRASIL

Chile Fecha Acordo com o MERCOSUL, *Jornal do Brasil*, 26 March 1996

JORNAL DO BRASIL

Venezuela Ingressará no MERCOSUL, *Jornal do Brasil*, 21 May 1996

KENDALL, S., S. Bowne, J. Mann & S. Fidler

Andean Pact Still Split on Outside Tariff, *Financial Times*, 12 May 1994, p. 6

KING, Stephen R.

The Source of Our Cures, *Cultural Survival Quarterly*, 1991, pp. 19-22

KLÖPSCH, Gerald

The Patentability of Pharmaceuticals According to the European Patent Convention (EPC), *International Review of Industrial Property and Copyright Law*, N. 4, 1982, pp. 457-470

KORAH, Valentine
European Commission's Tentative Views on Know-How Licensing, *European Intellectual Property Review*, N. 12, 1986, pp. 79-86

KORAH, Valentine
The Preliminary Draft of a New EC Group Exemption for Technology Licensing, *European Intellectual Property Review*, N. 7, 1994, pp. 263-286

KORS, Jorge A.
Nuevas Tecnologías y Derecho Industrial, *Revista del Derecho Industrial*, Vol. 41, 1992, pp.389-419

LAWRENCE, Robin
Patent Litigation Reform - In Europe?, *European Intellectual Property Review*, N. 2, 1982, pp. 39-41

LAWREY, Andrée
Contemporary Efforts to Guarantee Indigenous Rights Under International Law, *Vanderbilt Journal of Transnational Law*, Vol. 23, N. 4, 1990, pp. 703-777

LEITE, Rogério Cezar de Cerqueira
Patentes e Pressões Norte-Americanas, *Folha de São Paulo*, 5 May 1993, Caderno 2, p. 2

LEONARDOS, Gabriel Francisco, A Relação entre o Direito Antitruste e o Direito da Propriedade Industrial, paper presented during the 16th National Seminar of Industrial Property, São Paulo, Brazil, 20 August 1996

MANSFIELD, Edwin
Patents and Innovations: An Empirical Study, *Management Science*, February 1986, *apud* **Julio Nogués**, Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries, *Journal of World Trade*, N. 6, 1990, pp. 81-103

McCLELLAN, A.
The Convention of Brussels of September 27, 1968 on Jurisdiction, and the Recognition and Enforcement of Judgments in Civil and Commercial Matters, *Common Market Law Review*, Vol. 15, 1978, pp. 228-243

MEDEIROS, José Artur Denot
MERCOSUL: Quadro Normativo e Institucional Pós-Ouro Preto, *Boletim de Integração Latino-Americana*, N. 16, 1995 (*http://www.mre.gov.br/getec/webgetec/bila/16/1artigos/1denot.htm*)

MEZRICH, Jonathan L.
The Patentability and Patent Term Protection of Lifesaving Drugs: A Deadly Mistake, *Journal of the Patent and Trademark Office Society*, Vol. 74, N. 2, 1992, pp. 77-95

MILLER, Clifford G.
Magill: Time to Abandon the 'Specific Subject-Matter' Concept, *European Intellectual Property Review*, N. 10, 1994, pp. 415-421

MINISTÉRIO DAS RELAÇÕES EXTERIORES,
Quadro Demonstrativo de Patentes: MERCOSUL (1993)

MINISTRY OF SCIENCE AND TECHNOLOGY
SUSBIO: Sustainable Use of Biodiversity - A Strategy for the Use of Biodiversity Leading to Sustainable Development - Model Proposal for Brazil, *mimeo* (August 1994)

MOREL, Carlos Médici
Biossegurança: Uma Nova Ciência?, *Anais da 47a. Reunião Anual da Sociedade Brasileira para o Progresso da Ciência*, Vol. 1 (July 1995), pp. 25-26

MUGABE, John
Governing Access to Genetic Resources: Emerging National Policy, Legal and Administrative Regimes, paper presented at the Global Biodiversity Forum '95, Jakarta, Indonesia, 4-5 November 1995

NEUKON, John
A Prior Use Right for the Community Patent Convention, *European Intellectual Property Review*, N. 5, 1990, pp. 165-169

NEUKON, John
A Prior Use Right for the Community Patent Convention: An Update, *European Intellectual Property Review*, N. 4, 1991, pp. 139-141

NEUKON, John
What Price the Community Patent?, *European Intellectual Property Review*, N. 4, 1992, pp. 111-112

NOGUÉS, Julio
Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries, *Journal of World Trade*, N. 6, 1990, pp. 81-103

NOTT, Robin
The Proposed EC Directive on Biotechnological Inventions, *European Intellectual Property Review*, N. 5, 1994, pp. 191-194

ORGANIZATION OF AMERICAN STATES
Towards Free Trade in the Americas, (1995)
(*http://www.oas.org/frtrade.htm*)

PATERSON, Gerald
The Patentability of Further Uses of a Known Product under the European Patent Convention, *European Intellectual Property Review*, N. 1, 1991, pp. 16-20

PELKMANS, Jacques
The New Approach to Technical Harmonization and Standardization, *Journal of Common Market Studies*, Vol. 25, 1987, pp. 249-269

PEREIRA, José Matias
Regimes de Concorrência e Políticas de Concorrência na América Latina: o Caso do MERCOSUL, *Boletim de Integração Latino-Americana*, N. 16, 1995 (*http://www.mre.gov.br/getec/webgetec/bila/16/4nota.htm*)

POSEY, Darrell
Intellectual Property Rights and Just Compensation for Indigenous Knowledge, *Anthropology Today*, Vol. 6, N. 4, 1990, pp. 13-16

PUTTERMAN, Daniel
Model Material Transfer Agreements for Equitable Biodiversity Prospecting, *mimeo* (1995)

RASMUSSEN, Hjalte
A New Generation of Community Law? Reflections on the Handling by the Court of Justice of the Protocol of 1971 Relating to the Interpretation of the Brussels Convention on Jurisdiction and Enforcement of Judgments, *Common Market Law Review*, Vol. 15, 1978, pp. 249-282

REID, Walter
Biotechnology, Technological Change, and Regulation of Access to Genetic Resources, paper presented at the Global Biodiversity Forum '95, Jakarta, Indonesia, 4-5 November 1995

REINBOTH, Jörg & Anthony Howard
The State of Play in the Negotiations on Trips (GATT/Uruguay Round), *European Intellectual Property Review*, N. 5, 1991, pp. 157-164

ROSENN, Keith S.
Brazil - Supplement, in **Albert P. Blaustein & Gisbert H. Flanz**, Constitutions of the Countries of the World, New York: Oceana Publications Inc. (1993), Release 93-2

ROSS, Julie Chasen & Jessica A. Wasserman

Trade-Related Aspects of Intellectual Property Rights, in **Terence P. Stewart**, The GATT Uruguay Round: A Negotiating History (1986-1992), Deventer/The Netherlands: Kluwer Law and Taxation Publishers (1993)

ROTHLEY, Willi

European Parliament Must Think Again About Biotechnological Protection, *International Review of Industrial Property and Copyright Law*, N. 5, 1995, pp. 668-670

SCARTEZINI, Vanda

Letter from the INPI to the President of the ABPI, Juliana Laura Bruna Viegas (OF/INPI/PR/N. 62/96, of 25 April 1996)

SILVA, Carlos Eduardo Lins da

Comércio Exterior é Foco de Tensão com os EUA, *Folha de São Paulo*, 29 March 1996

SOCIEDADE BRASILEIRA PARA O PROGRESSO DA CIÊNCIA

Patentes em Discussão no Senado, *Jornal da Ciência Hoje*, 25 August 1995

SOLTYSINSKÍ, Stanislaw J.

Are Trade Secrets Property?, *International Review of Industrial Property and Copyright Law*, Vol. 17, 1986, pp. 331-356

SORSA, Piritta

GATT and Environment, *The World Economy*, N. 1, 1992, pp. 115-133

STAEHELIN, Jenö

The European Patent Organisation, *Yearbook of European Law*, Vol. 1, 1981, pp. 333-346

STIEGER, Werner

Article 54 (5) of the Munich Patent Convention: An Exception for Pharmaceuticals, *International Review of Industrial Property and Copyright Law*, N. 2, 1982, pp. 137-161

STONE, P. A.

Some Thoughts on the Windsurfing Judgment, *European Intellectual Property Review*, N. 8, pp. 242-248

STRAUS, Joseph

The Rio Biodiversity Convention and Intellectual Property, *International Review of Industrial Property and Copyright Law*, N. 5, 1993, pp. 602-615

SZABO, George S.A.

The Problem and Solution Approach in the European Patent Office, *International Review of Industrial Property and Copyright Law*, N. 4, 1995, pp. 457-487

TRITTON, Clare & Guy Tritton

The Brussels Convention and Intellectual Property, *European Intellectual Property Review*, N., 12, 1987, pp. 349-354

TRITTON, Guy

Articles 30 to 36 and Intellectual Property: Is the Jurisprudence of the ECJ Now of an Ideal Standard?, *European Intellectual Property Review*, N. 10, 1994, pp. 422-428

US GOVERNMENT

FTAA Working Group on Intellectual Property - Proposed Terms of Reference - 5 December 1995
(*http://americas.fiu.edu/documents/950630.htm*)

VIGNES, Daniel

The Harmonisation of National Legislation and the EEC, *European Law Review*, Vol. 15, 1990, pp. 358-374

VINJE, Thomas C.

Harmonising Intellectual Property Laws in the European Union: Past, Present and Future, *European Intellectual Property Review*, N. 8, 1995, pp. 361-377

VOGELAAR, T.W.

The Approximation of the Laws of Member States under the Treaty of Rome, *Common Market Law Review*, Vol. 12, 1975, pp.211-230

WADLON, C.M.

Intellectual Property and the Judgment Convention, *European Law Review*, Vol. 10, 1985, pp. 305-315

WANG, Lei

Some Observations on the Dispute Settlement System in the World Trade Organization, *Journal of World Trade*, Vol. 29, N. 2, 1995, pp. 173-178

WHAITE, Robin
The Draft Technology Transfer Block Exemption, *European Intellectual Property Review*, N. 7, 1994, pp. 259-262

WHITE HOUSE
Remarks by the President to Members of the Summit Community, Host Officials, and Officials from Florida on the Goals of the Summit (*gopher://summit.fiu.edu/00/Updates/clinton-remarks.txt*)

WORCEL, Gloria
El MERCOSUR en el Periodo de la Transicion: Funcionamento Institucional, Participación Empresaria y Impacto sobre el Comercio, Buenos Aires: CEPAL, Documento de Trabajo N. 44, LC/BUE/L.26, May 1992

ZALZUENDO, S.C.
Patentes en el Grupo Andino: Reforma de 1991, *Revista del Derecho Industrial*, N. 39, 1991, pp. 457-465

ZANCAN, Glaci
Patentes: Não para Vegetais e Animais, *Jornal da Ciência Hoje*, 25 August 1995

ZANON, L.
Ties in Patent Licensing Agreements, *European Law Review*, N. 5, 1980, pp. 391-399

Books

ALMEIDA, Paulo Roberto de
MERCOSUL: Legislação e Textos Básicos, Brasília: Senado Federal (1992)

ALMEIDA, Paulo Roberto de
O MERCOSUL no Contexto Regional e Internacional, São Paulo: Edições Aduaneiras Ltda. (1993)

BELLAMY, Christopher & Graham Child
Common Market Law of Competition, London: Sweet & Maxwell Ltd. (1987) 3rd ed.

BOGSCH, Arpad
Brief History of the First 25 Years of the World Intellectual Property Organization, Geneva: WIPO (1992)

BROWNLIE, Ian (ed.)
Basic Documents in International Law, Oxford: Clarendon Press (1983), 3rd ed.

BROWNLIE, Ian
Principles of Public International Law, Oxford: Oxford University Press (1990), 4th ed.

BURNETT-HALL, Richard
Environmental Law, London: Sweet & Maxwell (1995)

CERQUEIRA, João da Gama
Tratado da Propriedade Industrial, Vol. 1, Rio de Janeiro: Revista Forense (1946)

CERQUEIRA, João da Gama
Tratado da Propriedade Industrial, Vol. 2, Tomo I, Rio de Janeiro: Revista Forense (1952)

CERQUEIRA, João da Gama
Tratado da Propriedade Industrial, Vol. 2, Tomo II, Parte III, Rio de Janeiro: Revista Forense (1956)

CORNISH, W.R.
Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights, London: Sweet & Maxwell Ltd. (1989), 2nd ed.

COWIE, A.P. (ed.)
Oxford Advanced Learner's Dictionary, Oxford: Oxford University Press (1989), 4th ed.

DELL, Sidney
A Latin American Common Market?, London, New York and Toronto: Oxford University Press & the Royal Institute of International Affairs (1966)

DOMINGUES, Douglas Gabriel
Direito Industrial - Patentes, Rio de Janeiro: Companhia Editora Forense (1980)

DUVAL, Hermano
Concorrência Desleal, São Paulo: Editora Saraiva S.A. (1976)

ECO, Humberto
Como se Faz uma Tese, São Paulo: Editora Perspectiva S.A. (1989)

EDWARD, David A. O. & Robert C. Lane
European Community Law: An Introduction, Edinburgh: Butterwoths & Law Society of Scotland (1995), 2nd ed.

EMPEL, M. van
The Granting of European Patents, Leyden/The Netherlands: A.W. Sijthoff International Publishing Company B.V. (1975)

FARIA, José Ângelo Estrella
O MERCOSUL: Princípios, Finalidade e Alcance do Tratado de Asunção, Brasília: MRE/SGIE/NAT (1993)

FOSTER, Nigel (ed.)
Blackstone's EC Legislation, London: Blackstone Press Limited (1995), 6th ed.

FROTA, Maria Stela Pompeu Brasil
Patentes de Produtos Farmacêuticos: o Caso Brasileiro, Brasília: FUNAG/IRPI (1993)

GATT Analytical Index: Guide to GATT Law and Practice, Geneva: GATT (1994), 6th ed.

GLOWKA, Lyle, Françoise Burhenne-Guilmin & Hugh Synge (in collaboration with Jeffrey A. McNeely and Lothar Gündling) A Guide to the Convention on Biological Diversity, Gland/Switzerland and Cambridge/United Kingdom: IUCN (1994)

GOYDER, D.G.
EC Competition Law, Oxford: Oxford University Press (1993) 2nd ed.

GUY, Diana & Guy Leigh
The EEC and Intellectual Property, London: Sweet & Maxwell Ltd. (1981)

HANSEN, Roger D.
Central America: Regional Integration and Economic Development, Washington, DC: National Planning Association (1967)

HELTER, Tom
Poor Health, Rich Profits: Multinational Drug Companies and the Third World, Nottingham: Spokesman Books (1977)

INPI Legislação da Propriedade Industrial e do Comércio de Tecnologia (Seleção, compilação e notas por Denis Borges Barbosa), Rio de Janeiro: Editora Forense (1982)

INTER-AMERICAN DEVELOPMENT BANK & INSTITUTE FOR LATIN AMERICAN INTEGRATION Economic and Social Progress in Latin America - Economic Integration (1984 report), Washington, DC: Inter-American Development Bank (1984)

INTER-AMERICAN INSTITUTE OF INTERNATIONAL LEGAL STUDIES Instruments Relating to the Economic Integration of Latin America, New York: Oceana Publications, Inc. (1968)

JACKSON, John H.
Restructuring the GATT System, London: Royal Institute of International Affairs (1990)

JACKSON, John H.
The World Trading System: Law and Policy of International Economic Relations, Massachusetts: The MIT Press (1989)

JESUS, Avelino de
Relações Comerciais Internacionais: GATT, ALADI, MERCOSUL, SGP, SGPC, NCPD, São Paulo: Edições Aduaneiras (1992)

KOLKER, Peter
Should Importation Be Considered as Working? A Study of Article 27 of the GATT/TRIPS Agreement, London: The Intellectual Property Institute (1996)

KORAH, Valentine
Patent Licensing and EEC Competition Law - Regulation 2349/84, Oxford: ESC Publishing Limited (1985)

LASOK, D. & J.W. Bridge
Law and Institutions of the European Communities, London & Edinburgh: Butterworths & Co. (Publishers) Ltd. (1991), 5th ed.

LEDOGAR, Robert J.
Hungry for Profits: US Food and Drug Multinationals in Latin America, New York: IDOC/North America, Inc. (1975)

LESSER, W.
Institutional Mechanisms Supporting Trade in Genetic Materials: Issues under the Biodiversity Convention and GATT/TRIPS, Geneva: UNEP (1994)

MELLO, Celso D. de Albuquerque
Direito Internacional Econômico, Rio de Janeiro: Renovar (1993)

MINISTÉRIO DAS RELAÇÕES EXTERIORES & FUNDAÇÃO CENTRO DE ESTUDOS DE COMÉRCIO EXTERIOR O Brasil e o NAFTA: Impacto Sobre Comércio e Investimentos, Brasília: ABIGRAF (1993)

OLIVEIRA, Juarez de
Código Civil, São Paulo: Editora Saraiva (1987), 37th ed.

OLIVER, Peter
Free Movement of Goods in the EEC under Articles 30 to 36 of the Rome Treaty, London: European Law Centre Limited (1982)

OUDEMANS, G.
The Draft European Patent Convention: A Commentary with English and French Texts, London: Stevens and Sons Limited (1963)

PATERSON, Gerald
The European Patent System: The Law and Practice of the European Patent Convention, Oxford: Sweet & Maxwell Ltd. (1992)

PHILLIPS, Jeremy & Alison Firth
Introduction to Intellectual Property Law, London, Dublin and Edinburgh: Butterworth & Co (Publishers) Ltd. (1990), 2nd ed.

POSEY, Darrell & Graham Dutfield
Beyond Intellectual Property Rights: Towards Traditional Resource Rights for Indigenous and Local Communities, Gland/Switzerland and Ottawa: WWF-International & IDRC (forthcoming)

REBELO, Aldo (ed.)
Lei das Patentes e Soberania Nacional, Brasília: Coordenação de Publicações, Câmara dos Deputados (1992)

REEKIE, W. Duncan
The Economics of the Pharmaceutical Industry, London and Basingstoke: The MacMillan Press Ltd. (1975)

ROSE, Vivien (ed.), Bellamy & Child Common Market Law of Competition, London: Sweet & Maxwell (1993) 4th ed.

SHAW, Malcom N.
International Law, Cambridge/United Kingdom: Grotius Publications Limited (1991), 3rd ed.

SILVA, José Afonso da
Curso de Direito Constitucional Positivo, São Paulo: Editora Revista dos Tribunais (1991), 7th ed.

STEWART, Terence P. (ed.)
The GATT Uruguay Round: A Negotiating History (1986-1992), Deventer/The Netherlands: Kluwer Law and Taxation Publishers (1993)

TACHINARDI, Maria Helena
A Guerra das Patentes - O Conflito Brasil x EUA sobre Propriedade Intelectual, Rio de Janeiro: Editora Paz e Terra S.A. (1993)

TWITCHETT, Carol C. (ed.)
Harmonisation in the EEC, London: The MacMillan Press Ltd. (1981)

UPOV The First Twenty-Five Years of the International Convention for the Protection of New Varieties of Plants, Geneva: UPOV (1987)

URQUIDI, Victor L.
Free Trade and Economic Integration in Latin America: The Evolution of a Common Market Policy, Berkeley and Los Angeles: University of California Press (1968), 4th printing

WEISS, Edith Brown (ed.)
Environmental Change and International Law, Tokyo: United Nations University Press (1992)

WHISH, Richard
Competition Law, London: Butterworth and Co. (Publishers) Ltd. (1989) 2nd ed.

WIPO Protection Against Unfair Competition, Geneva: WIPO (1994)

WOLFRUM, Rüdiger & C. Philipp (ed.)
United Nations: Law, Policies and Practice, London: Martinus Nijhoff Publishers (1995), Vols. 1 and 2

WYATT, Derrick & Alan Dashwood
European Community Law, London: Sweet & Maxwell Ltd. (1993) 3rd ed.

WYATT, Derrick & Alan Dashwood
The Substantive Law of the EEC, London: Sweet & Maxwell (1987), 2nd ed.

Cases from the European Court of Justice, European Court of First Instance & National Courts (Alphabetical Order)

Allen and Hanburys* v. *Generics (Case 434/85) [1988] ECR 1425, [1988] 1 CMLR 701

Bayer* v. *Sülhofer (Case 65/86) [1988] ECR 5249, [1990] 4 CMLR 182

Belgische Radio en Televisie* v. *Sabam (Case 127/73) [1974] ECR 313, [1974] 2 CMLR 238

Centrafarm* v. *Sterling Drug (Joined Cases 15 & 16/74) [1974] ECR-II 1147, [1974] 2 CMLR 480

Consten & Grundig* v. *Commission (Joined Cases 56 & 58/64) [1966] ECR 299, [1966] CMLR 418

Deutsche Grammophon* v. *Firma Pop (National Court - Germany) [1982] 1 CMLR 137 (BGH)

Deutsche Grammophon* v. *Metro (Case 78/70) [1971] ECR 487, [1971] CMLR 631

Eurofix-Bauco* v. *Hilti OJ 1988 L65/19, [1989] 4 CMLR 677

Flugkostenminimierung BGH Case N. XZR 65/85 GRUR 1986, 531 (in **Gerald Paterson**, The European Patent System: The Law and Practice of the European Patent Convention, Oxford: Sweet & Maxwell Ltd. (1992))

Hoffmann-La Roche* v. *Commission (Case 85/76) [1979] ECR 461, [1979] 3 CMLR 211

L.C. Nungesser KG and Kurt Eisele* v. *Commission (Case 258/78) [1982] ECR 2015, [1983] 1 CMLR 278

Merck & Co. Inc. and others* v. *Primecrown Ltd and others (Patent Court - England) [1995] *Fleet Street Reports* 909

Merck & Co.* v. *Stephar and Exler (Case 187/80) [1981] ECR 2063, [1981] 3 CMLR 463

Nungesser* v. *Commission (Case 258/78) [1982] ECR 2015, [1983] 1 CMLR 278

Parke, Davis & Co.* v. *Centrafarm (Case 24/67) [1968] ECR 55, [1968] CMLR 47

Pharmon* v. *Hoechst (Case 19/84) [1985] ECR 2281, [1985] 3 CMLR 775

Publico Ministero* v. *Ratti (Case 148/78) [1979] ECR 1629, [1980] 1 CMLR 96

RTE and ITP* v. *Commission (Joined Cases C-241/91 P and C-242/91 P) [1995] ECR-I 743

Sirena* v. *Eda (Case 40/70) [1971] ECR 69, [1971] CMLR 260

Société Technique* v. *Maschinenbau Ulm (Case 56/65) [1966] ECR 235, [1966] CMLR 357

Terrapin* v. *Terranova (Case 119/75) [1976] ECR 1039, [1976] 2 CMLR 482

Tetra Pak* v. *Commission (Case T-51/89) [1990] ECR II-309, [1991] 4 CMLR 334

The Who Group* v. *Stage One Records (National Court - England) [1980] 2 CMLR 429 (CD)

United Brands* v. *Commission (Case 27/76) [1978] ECR 207, [1978] 1 CMLR 429

Vand Gend en Loss* v. *Nederlandse Tariefcommissie (Case 26/62) [1963] ECR 1, [1963] 1 CMLR 105

Windsurfing International* v. *Commission (Case 193/83) [1986] ECR 611, [1986] CMLR 489

Decisions from the Commission of the European Communities (Alphabetical Order)

AOIP/Beyrard OJ 1976 L6/8, [1976] 1 CMLR D14

BBC/Brown Boveri OJ 1988 L301/68, [1988] 4 CMLR 427

Bronbemaling/Heidemaatschapij OJ 1975 L249/27, [1975] 2 CMLR D67

Burroughs/Delplanque OJ 1972 L13/50, [1974] CMLR D67

Burroughs/Geha OJ 1972 L13/53, [1972] 4 CMLR D72

Davidson Rubber OJ 1972 L143/31, [1974] CMLR D52

Delta Chemie/DDD OJ 1988 L309/34, [1989] 4 CMLR 535

Kabelmetal/Luchaire OJ 1975 L222/34, [1975] 2 CMLR D40

Maize seeds OJ 1978 L286, [1978] 3 CMLR 434

Raymond/Nagoya OJ 1972 L143/39, [1972] CMLR D45

Re Campari OJ 1978 L70/69, [1978] 2 CMLR 397

Re the Franco-Japanese Ballbearings Agreement OJ 1974 L343/19, [1975] 1 CMLR D8

Rich Products/Jus-rol OJ 1988 L69/21, [1988] 4 CMLR 527

Tetra Pak I (BTG Licence) OJ 1988 L272/77

Vaessen Morris OJ 1979 L19/32, [1979] 1 CMLR 511

Video Cassette Recorders OJ 1978 L47/42, [1978] 2 CMLR 160

Decisions of the European Patent Office (Alphabetical Order)

BASF/Metal refining (T24/81) [1974-85] EPOR: B: 414

BAYER/Carbonless copying paper (T1/80) [1981] *Offical Journal EPO* 206

BEATTIE/Marker (T603/89) of 3 July 1990 (P) (in **Gerald Paterson**, The European Patent System: The Law and Practice of the European Patent Convention, Oxford: Sweet & Maxwell Ltd. (1992))

BIOGEN/Alpha-interpherons (T301/87) [1990] EPOR 190

BRUKER/Non-invasive measurement (T385/86) [1988] EPOR 357

BRUKER/Non-invasive measurement (T385/86) [1988] EPOR 357

DU PONT/Appetite suppressant (T144/83) [1987] EPOR 6

EISAI/Second medical indication (G5/83) [1979-85] EPOR: B: 241

HARVARD/Onco-mouse (Application 85 304 490.7 of 14 July 1989) [1990] EPOR 4

HARVARD/Onco-mouse (T19/90) [1990] EPOR 50

HOECHST/Polyvinyl ester dispersion (T93/89) of 15 November 1990 (in **Gerald Paterson**, The European Patent System: The Law and Practice of the European Patent Convention, Oxford: Sweet & Maxwell Ltd. (1992))

IBM/Computer-related invention (T115/85) [1990] EPOR 107

LUCHTENBER/Rear-view mirror (T84/83) [1979-85] EPOR: C: 796

MOBIL OIL/Friction reducing additive (G2/88) [1990] EPOR 73

RESEARCH CORPORATION/Publication (T381/87) [1989} EPOR 138

ROUSSEL-UCLAF/Thenoyl peroxide (T36/83) [1987] EPOR 1

TÉLÉMÉCANIQUE/Electrical supply (T482/89) of 11 December 1990 (in **Gerald Paterson**, The European Patent System: The Law and Practice of the European Patent Convention, Oxford: Sweet & Maxwell Ltd. (1992))

VICOM/Computer-related invention (T208/84) [1986] EPOR 74

WELLCOME/Pigs I (T116/85) [1988] EPOR 1

National and International Legislative and Legal Materials (Alphabetical Order)

ABPI Decreto N. 635, de 21 de agosto de 1992 (Promulga a Convenção de Paris para a Proteção da Propriedade Industrial, revista em Estocolmo a 14 de julho de 1967), Rio de Janeiro: *Revista da ABPI - Separata*, 1994 (reedição)

AGREEMENT ON ARGENTINE-BRAZILIAN INTEGRATION
International Legal Materials, Vol. 27, 1988, p. 901

BIRPI Paris Convention for the Protection of Industrial Property (of March 20, 1883, as revised at Brussels, on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967), Geneva: BIRPI (1968)

BRAZIL & BOLIVIA
Agreement for Economic Co-operation, of 27 January 1994, *Boletim de Integração Latino-Americana*, N. 13, 1994, pp. 192-209

BRAZIL & CHILE

Agreement for Reciprocal Protection of Investments, of 22 March 1994, *Boletim de Integração Latino-Americana*, N. 13, 1994, pp. 210-215

BRAZIL & VENEZUELA

Agreement for Economic Co-operation, of 15 July 1994, *Boletim de Integração Latino-Americana*, N. 14, 1994, pp. 260-265

CÂMARA DOS DEPUTADOS

10a. Reunião Ordinária da Comissão Especial de Propriedade Industrial (12/03/92)

CÂMARA DOS DEPUTADOS

12a. Reunião Ordinária da Comissão Especial de Propriedade Industrial (07/04/92)

CÂMARA DOS DEPUTADOS

7a. Reunião Ordinária da Comissão Especial de Propriedade Industrial (10/12/91)

CÂMARA DOS DEPUTADOS

Projeto de Lei N. 2.057, de 1991, of 23 October 1991, Brasília: Câmara dos Deputados (1991)

CÂMARA DOS DEPUTADOS

Projeto de Lei N. 824, de 1991, of 30 April 1991 (Mensagem Presidencial 192/91 - Do Poder Executivo), Brasília: Câmara dos Deputados (1991)

COMMISISON OF THE EUROPEAN COMMUNITIES

Completing the Internal Market - White Paper from the Commission to the European Council (Milan, 28-29 June 1985), COM(85) 310 final

COMMISSION OF THE EUROPEAN COMMUNITIES

Draft Interpretative Declaration (on the occasion of the ratification of the Convention on Biological Diversity, (16 April 1993) (not published)

COMMISSION OF THE EUROPEAN COMMUNITIES

Fourth Report on Competition Policy, Brussels & Luxembourg (1975)

COMMISSION OF THE EUROPEAN COMMUNITIES

Ninth Report on Competition Policy, Brussels & Luxembourg (1980)

COMMISSION OF THE EUROPEAN COMMUNITIES

Notice on Agreements of Minor Importance, OJ 1986 C231/2

COMMISSION OF THE EUROPEAN COMMUNITIES
Notice on Patent Licensing Agreements, OJ, Special Edition, 1962 C139/2922 (withdrawn in OJ 1984 C220/14)

COMMISSION OF THE EUROPEAN COMMUNITIES
Panorama of EC Industry 1991-1992, Luxembourg: Office for Official Publications of the European Communities (1991)

COMMISSION OF THE EUROPEAN COMMUNITIES
Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, OJ 1993 C44/36

COMMISSION OF THE EUROPEAN COMMUNITIES
Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions, COM(95) 661 final, 13 December 1995

COMMISSION OF THE EUROPEAN COMMUNITIES
Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, of 13 December 1995, COM(95) 666 final

COMMISSION OF THE EUROPEAN COMMUNITIES
Tenth Report on Competition Policy, Brussels & Luxembourg (1981)

COMMISSION OF THE EUROPEAN COMMUNITIES
Twentieth Report on Competition Policy, Brussels (1991)

COMMISSION OF THE EUROPEAN COMMUNITIES
Twenty First Report on Competition Policy, Brussels & Luxembourg (1992)

COMMISSION OF THE EUROPEAN COMMUNTIES
Fifteenth Report on Competition Policy, Brussels & Luxembourg (1986)

CONVENTION ON THE GRANT OF EUROPEAN PATENTS (EUROPEAN PATENT CONVENTION) in **Gerald Paterson**, The European Patent System: The Law and Practice of the European Patent Convention, Oxford: Sweet & Maxwell Ltd. (1992), Appendix 1

CONVENTION ON THE UNIFICATION OF CERTAIN POINTS OF SUBSTANTIVE LAW ON PATENTS FOR INVENTIONS of 27 November 1963, *Industrial Property*, Vol. 3, 1964, p. 13

COUNCIL OF THE EUROPEAN COMMUNITIES

Regulation N. 17 - First Regulation implementing Articles 85 and 86 of the Treaty, of 6 February 1962, OJ, Special Edition, 21/2/62, 87

COUNCIL OF THE EUROPEAN COMMUNITIES

Regulation N. 1768, of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ 1992 L182/1

COUNCIL OF THE EUROPEAN COMMUNITIES

Regulation N. 19/65, OJ, Special Edition, 1965-1966, 35, 1965, 533

COUNCIL OF THE EUROPEAN COMMUNITIES

Regulation N. 2.100/94 of 27 July 1994 on Community plant variety rights, OJ 1994 L227/1

COUNCIL OF THE EUROPEAN COMMUNITIES

Regulation N. 2349 on the application of Article 85 (3) of the Treaty to certain categories of patent licensing agreement, of 23 July 1984, OJ 1984 L219/15 (*corrigendum* OJ 1985 L113/34), as amended by Regulation 151/93 (OJ 1993 L21/8)

COUNCIL OF THE EUROPEAN COMMUNITIES

Regulation N. 240 on the application Article 85 (3) of the Treaty to certain categories of technology transfer agreements, of 31 January 1996, OJ 1996 L31/2

COUNCIL OF THE EUROPEAN COMMUNITIES

Regulation N. 3.385/94, OJ 1994 L377/28

COUNCIL OF THE EUROPEAN COMMUNITIES

Regulation N. 556 on the application of Article 85 (3) of the Treaty to certain categories of know-how licensing agreements, of 30 November 1988, OJ 1989 L61/1, as amended by Regulation 151/93 (OJ 1993 L21/8)

EUROPEAN COMMUNITY

Convention for the European Patent for the Common Market (Community Patent Convention, OJ 1976 L17 (as amended by the Agreement Relating to Community Patents - Done at Luxembourg on 15 December 1989, OJ 1989 L401)

EUROPEAN COMMUNITY

Convention on Jurisdiction and Enforcement of Judgment in Civil and Commercial Matters, of 27 September 1968, OJ 1978 L304

EUROPEAN COMMUNITY
Protocol on a possible modification of the conditions of entry into force of the Agreement relating to Community Patents OJ 1989 L401/51

EUROPEAN COMMUNITY
Report from the President of the Lisbon Conference on the Community Patent to the EC Council, N. 7373/92, EN

EUROPEAN COMMUNITY
Texts Established by the Luxembourg Conference on the Community Patent 1985 (1986)

EUROPEAN COMMUNITY
Treaty Establishing the European Community (as amended by the Treaty Ameding Certain Financial Provisions, the Single European Act, the Merger Treaty, the Greenland Treaty, the Acts of Accession and the Treaty on European Union, in **Nigel Foster** (ed.) Blackstone's EC Legislation, London: Blackstone Press Limited (1995), 6th ed.

EUROPEAN CONVENTION RELATING TO THE FORMALITIES REQUIRED FOR PATENT APPLICATIONS *Industrial Property*, Vol. 19, 1980, p. 21

FTAA Americas Business Forum, Cartagena de Indias Colombia, March 18-21, 1996 (*http://americas.fiu.edu/documents/960130.htm*)

FTAA Cartagena Declaration, 21 March 1996 (*http://americas.fiu.edu/documents/960321a.htm*)

FTAA Declaration of Principles; Partnership for Development and Prosperity: Democracy, Free Trade and Sustainable Development in the Americas, in *Boletim de Integração Latino-Americana*, N. 15, 1994, pp. 241-244

FTAA Denver Declaration (*http://americas.fiu.edu/documents/950630.htm*)

FTAA FTAA Working Group on Intellectual Property - Proposed Terms of Reference, 5 December 1995 (*http://americas.fiu.edu/inside/index.html*)

FTAA Plan of Action, in *Boletim de Integração Latino-Americana*, N. 15, 1994, pp. 244-260

FTAA Second Trade Ministerial Meeting, Cartagena de Indias, 18-21 March 1996 (*http://americas.fiu.edu/documents/960321.htm*)

FTAA The Americas Business Forum, Cartagena de Indias, Colombia, 18-21 March 1996 (*http://americas.fiu.edu/documents/960130.htm*)

GATT Draft Amendment to the General Agreement on Tariffs and Trade on the Protection of Trade-Related Intellectual Property Rights, Communication from Switzerland, Document N. MTN.GNG/NG11/W/73 (14 May 1990)

GATT Checklist of Issues, Prepared by the Secretariat, (26 January 1990)

GATT Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, Document N. MTN.GNG/NG11/W/71 (14 May 1990)

GATT Communication from Brazil, Document N. MTN.GNG/NG11/W/57 (11 December 1989)

GATT Communication from Chile, Document N. MTN.GNG/NG11/W/61 (22 January 1990)

GATT Compilation of Written Submissions and Oral Statements, Prepared by the Secretariat, Revision, Document N. MTN.GNG/NG11/W/12/Rev.1 (3 February 1988)

GATT Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights, Communication from the United States, Document N. MTN.GNG/NG11/W/70 (11 May 1990)

GATT Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, Document N. MTN.GNG/NG11/W/68 (29 March 1990)

GATT Draft Agreement to Discourage the Importation of Counterfeit Goods, Document N. MTN.GNG/NG11/W/9 (25 June 1987)

GATT Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Note Prepared by the International Bureau of WIPO, Document N. MTN.GNG/NG11/W/24/Rev.1 (15 September 1988)

GATT GATT Provisions Bearing on Trade-Related Aspects of Intellectual Property Rights, Note by the Secretariat, Document N. MTN.GNG/NG11/W/6 (22 May 1987)

GATT Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards for Intellectual Property Rights, Document N. MTN.GNG/NG11/W/26 (7 July 1988)

GATT Guidelines Proposed by the European Community for the Negotiations on Trade-Related Aspects of Intellectual Property Rights, Document N. MTN.GNG/NG11/W/15 (20 November 1987)

GATT India - Statement by Dr. Subramanian Swany, Union Minister of Commerce, Law and Justice, Document N. MTN.TNC/MIN(90)/ST/46 (4 December 1990)

GATT Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations, *International Legal Materials*, Vol. 25, 1986, p. 1623

GATT National Legislation and Practices Deemed Restrictive in Connection with Intellectual Property Rights, Note by the Secretariat, Document N. MTN.GNG/NG11/W/64 (1 February 1990)

GATT Standards for Trade-Related Intellectual Property Rights, Submission from Canada, Document N. MTN.GNG/NG11/W/47 (25 October 1989)

GATT Statement by the United States at Meeting of 25 March 1987, Document N. MTN.GNG/NG11/W/2 (3 April 1987)

GATT Submission by Japan - Addendum, Document N. MTN.GNG/NG11/W/17/Add.3 (8 December 1989)

GATT Submission from Brazil, Document N. MTN.GNG/NG11/W/30 (31 December 1988)

GATT Submissions from Participants on Trade Problems Encountered in Connection with Intellectual Property Rights, Document N. MTN.GNG/NG11/W/7 (29 May 1987)

GATT Suggestion by Japan for Achieving the Negotiating Objective, Document N. MTN.GNG/NG11/W/17 (23 November 1987)

GATT Suggestion by the United States for Achieving the Negotiating Objective - Revision, Document N. MTN.GNG/NG11/W/14/Rev.1 (17 October 1988)

GATT Synoptic Table Setting Out Existing International Standards and Proposed Standards and Principles, Prepared by the Secretariat, Revision, Document N. MTN.GNG/NG11/W/32/Rev.2 (2 February 1990)

GATT Text of the General Agreement, Geneva: GATT (1986)

GATT The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts, Geneva: GATT Secretariat (1994)

GATT Work Undertaken in GATT Concerning Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Note by the Secretariat, Document N. MTN.GNG/NG11/W/4 (6 May 1987)

INPI Apêndice da Legislação da Propriedade Industrial e do Comércio de Tecnologia (Seleção, compilação e notas por Denis Borges Barbosa com a colaboração de Paulo Olinto), Rio de Janeiro: Editora Forense, 1983

INPI Ato Normativo N. 17, de 11 de maio de 1976 (in **INPI** Legislação da Propriedade Industrial e do Comércio de Tecnologia (Seleção, compilação e notas por Denis Borges Barbosa), Rio de Janeiro, Brazil: Editora Forense (1982))

INPI Ato Normativo N. 19, de 11 de maio de 1976 (in **INPI** Legislação da Propriedade Industrial e do Comércio de Tecnologia (Seleção, compilação e notas por Denis Borges Barbosa), Rio de Janeiro, Brazil: Editora Forense (1982))

INPI Lei N. 5.772, de 21 de dezembro de 1971 - Institui o novo Código de Propriedade Industrial e dá outras providências (in **INPI** Legislação da Propriedade Industrial e do Comércio de Tecnologia (Seleção, compilação e notas por Denis Borges Barbosa), Rio de Janeiro, Brazil: Editora Forense (1982))

LAFTA Protocol Institutionalizing the Council of Ministers of Foreign Affairs of the Latin American Free Trade Association, in **Inter-American Institute of International Legal Studies**, Instruments Relating to the Economic Integration of Latin America, New York: Oceana Publications, Inc. (1968), pp. 318-321

LAFTA Resolution 117 (V), Fifth Regular Session, Montevideo, December 30, 1965), in **Inter-American Institute of International Legal Studies**, Instruments Relating to the Economic Integration of Latin America, New York: Oceana Publications, Inc. (1968), pp. 317-318

LAFTA Treaty Establishing a Free Trade Area and Instituting the Latin American Free Trade Association, in **Inter-American Institute of International Legal Studies**, Instruments Relating to the Economic Integration of Latin America, New York: Oceana Publications, Inc. (1968), pp. 207-229

LAIA Tratado de Montevidéu (12/08/1980), in MERCOSUL: Legislação e Textos Básicos, Brasília/DF: Senado Federal (1992), pp. 32-54

LEI N. 8.884, DE 11 DE JUNHO DE 1994 - TRANSFORMA O CONSELHO ADMINISTRATIVO DE DEFESA ECONÔMICA - CADE EM AUTARQUIA, DISPÕE SOBRE A PREVENÇÃO E A REPRESSÃO ÀS INFRAÇÕES CONTRA A ORDEM ECONÔMICA E DÁ OUTRAS PROVIDÊNCIAS, *Diário Oficial* de 13 de Junho de 1994, Seção 1, pp. 8437-8443

LEI N. 9.279, DE 14 DE MAIO DE 1996 - REGULA DIREITOS E OBRIGAÇÕES RELATIVOS À PROPRIEDADE INDUSTRIAL (in *Diário Oficial* de 15 de Maio de 1996, Seção 1, pp. 8353-8366

MERCOSUL Additional Protocol to the Treaty of Asuncion on the Institutional Structure of MERCOSUL, in *International Legal Materials*, Vol. 34, 1995, p. 1244

MERCOSUL Agreement Concerning a Council on Trade and Investment, in *International Legal Materials*, Vol. 30, 1991, p. 1034 (English version); and in **Paulo Roberto de Almeida**, MERCOSUL: Legislação e Textos Básicos, Brasília: Senado Federal (1992), pp. 123-128 (Portuguese version)

MERCOSUL Agreement for Economic Co-operation (with Bolivia), in *Boletim de Integração Latino-Americana*, N. 13, April/June 1994, pp. 192-209

MERCOSUL Agreement for Economic Co-operation (with Venezuela), in *Boletim de Integração Latino-Americana*, N. 14, July/September 1994, pp. 260-265

MERCOSUL Agreement for Reciprocal Protection of Investments (with Chile), in *Boletim de Integração Latino Americana*, N. 13, April/June 1994, pp. 210-215

MERCOSUL Agreement on Inter-Institutional Co-operation between the European Communities and the Common Market of the South, in **Paulo Roberto de Almeida**, MERCOSUL: Legislação e Textos Básicos, Brasília: Senado Federal (1992), pp. 129-131

MERCOSUL Ata da Reunião da Comissão de Propriedade Intelectual do MERCOSUL/SGT-7 (em 26 e 27 de setembro de 1994)

MERCOSUL Decision of the Council of the Common Market MERCOSUL/CMC/DEC. N. 1/1991, *Boletim de Integração Latino-Americana*, Special Edition, 1993, p. 30

MERCOSUL Decision of the Council of the Common Market MERCOSUL/CMC/DEC. N. 2/1991, *Boletim de Integração Latino-Americana*, Special Edition, 1993, p. 30

MERCOSUL First Meeting of the Committee of Technical Co-operation of CMG (19-20 November 1992), *Boletim de Integração Latino-Americana*, N. 8, 1993, pp. 55-57

MERCOSUL Joint Communication of the Presidents of the Countries of the MERCOSUL, of 17 December 1994 (not published)

MERCOSUL Landmark Inter-Regional Agreement for Co-operation Between the European Community and its Member States and the Common Market of the South and its States Parties, of 15 December 1995 (not published)

MERCOSUL Proposta Brasileira de Acordo Visando à Harmonização de Leis em Matéria de Propriedade Industrial entre os Países Integrantes do Mercosul, *mimeo*, December 1994

MERCOSUL Protocol of Brasilia for the Settlement of Disputes (MERCOSUL/CMC/DEC. N.1/1991, of 17 December 1991), published in **Paulo Roberto de Almeida**, MERCOSUL: Legislação e Textos Básicos, Brasília: Senado Federal (1992), pp. 132-140

MERCOSUL Resolution of the Common Market Group MERCOSUL/GMC/RES. N. 11/1991, *Boletim de Integração Latino-Americana*, Special Edition, 1993, p. 100

MERCOSUL Resolution of the Common Market Group MERCOSUL/GMC/RES. N. 11/1992, *Boletim de Integração Latino-Americana*, N. 4, 1992, p. 25

MERCOSUL Resolution of the Common Market Group MERCOSUL/GMC/RES. N. 25/92, *Boletim de Integração Latino-Americana*, N. 7, 1992, p. 37

MERCOSUL Treaty Establishing a Common Market Between the Argentine Republic, the Federative Republic of Brazil, the Republic of Paraguay and the Eastern Republic of Uruguay, of 26 March 1991, in *International Legal Materials*, Vol. 30, 1991, p. 1041

SENADO FEDERAL Projeto de Lei da Câmara N. 115, de 1993 (De iniciativa do Presidente da República - N. 824/91, na Casa de Origem), Brasília: Senado Federal (1993)

SENADO FEDERAL Projeto de Lei do Senado N. 199, of 22 June 1995, Brasília: Senado Federal (1995)

SENADO FEDERAL Projeto de Lei N. 306, de 1995, of 9 November 1995, Brasília: Senado Federal (1995)

TREATY OF INTEGRATION, CO-OPERATION AND DEVELOPMENT in **Paulo Roberto de Almeida**, MERCOSUL: Legislação e Textos Básicos, Brasília: Senado Federal (1992), pp. 27-31

TREATY ON INTELLECTUAL PROPERTY IN RESPECT OF INTEGRATED CIRCUITS, *International Legal Materials*, Vol. 28, 1989, p. 1477

UNCED Agenda 21, published in Earth Summit 1992, London: The Regency Press Corporation (1992)

UNCED Convention on Biological Diversity, *International Legal Materials*, Vol. 31, 1992, p. 818

UNCED Framework Convention on Climate Change, *International Legal Materials*, Vol. 31, 1992, p. 849

UNCED Rio Declaration on Environment and Development, *International Legal Materials*, Vol. 31, 1992, p. 874

UNCED Statement of Principles for a Global Consensus on the Management, Conservation and Sustainable Development of all Types of Forests, *International Legal Materials*, Vol. 31, 1992, p. 881

UNCHE Action Plan for the Human Environment, *International Legal Materials*, Vol. 11, 1972, p. 1421

UNCHE Declaration on the Human Environment, *International Legal Materials*, Vol. 11, 1972, p. 1416

UNCHE Resolution on Institutional and Financial Arrangements, *International Legal Materials*, Vol. 11, 1972, p. 1466

UNEP Biotechnology: Concepts and Issues for Consideration in Preparation of a Framework Legal Instrument for the Conservation of Biological Diversity, Document N. UNEP/Bio.Div.3/Inf.5 (23 May 1990)

UNEP Access to Genetic Resources and Benefit-Sharing: Legislation, Administrative and Policy Information, Document N. UNEP/CBD/COP/2/13 (6 October 1995)

UNEP Establishment of the Clearing-House Mechanism to Promote and Facilitate Technical and Scientific Co-operation, Document N. UNEP/CBD/COP/2/6 (29 September 1995)

UNEP Expert Panels Established to Follow-UP on the Convention on Biological Diversity - Technology Transfer and Financial Issues: Issues and Options from Panel III, Document N. UNEP/Bio.Div./Panels/Inf.3 (28 April 1993)

UNEP Experts Panels Established to Follow-Up on the Convention on Biological Diversity - Report of Panel II: Evaluation of Potential Economic Implications of Conservation and Its Sustainable Use and Evaluation of Biological and Genetic Resources, Document N. UNEP/Bio.Div./Panels/Inf.2 (28 April 1993)

UNEP Experts Panels Established to Follow-Up on the Convention on Biological Diversity - Report of Panel IV: Consideration of the Need for and Modalities of a Protocol Setting Out Appropriate Procedures Including, in Particular, Advance Informed Agreement in the Field of the Safe Transfer, Handling and Use of Any Living Modified Organism Resulting from Biotechnology that May Have Adverse Effect on the Conservation and Sustainable Use of Biological Diversity, Document N. UNEP/Bio.Div./Panels/Inf.4 (28 April 1993)

UNEP Report of the Open-ended Ad Hoc Group of Experts on Biosafety, Document N. UNEP/CBD/COP/2/7 (3 August 1995)

UPOV International Convention for the Protection of New Varieties of Plants of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991, Geneva: International Union for the Protection of New Varieties of Plants (1992)

UPOV Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, Geneva: UPOV (1991)

UPOV The Protection of Plant Varieties and the Debate on Biotechnological Inventions, presented for the information meeting of January 10, 1986, Document N. UPOV/INF/11 (10 December 1985)

US GOVERNMENT Public Papers of the President of the United States, Harry S. Truman - January 1 to December 31, 1949, Washington, DC: United States Government Printing Office (1964)

WIPO Analisis Selectivo de la Legislacion de Propiedad Industrial de los Paises del MERCOSUR, Preparado por la Oficina Internacional de la OMPI (22/3/93)

WIPO Patent Cooperation Treaty, of 19 June 1970, *International Legal Materials*, Vol. 9, 1970, p. 978

WIPO Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure, of April 28, 1977 and amended on 26 September 1980, Geneva: WIPO (1989)

WIPO Committee of Experts on Biotechnological Inventions and Industrial Property, Third Session, Geneva, June 29 to July 3, 1987, Document N. BioT/CE/III/3 (3 July 1987)

WIPO Committee of Experts on Biotechnological Inventions and Industrial Property, First Session, Geneva, November 5 to 9, 1984, Document N. BioT/CE/I/3 (9 November 1984)

WIPO Committee of Experts on Biotechnological Inventions and Industrial Property, Second Session, Genera, February 3 to 7, 1986, Document N. BioT/CE/II/3 (7 February 1986)

WIPO Convention Establishing the World Intellectual Property Organization, of 14 July 1967, *International Legal Materials*, Vol. 6, 1967, p. 782

WIPO Propuesta de Disposiciones Legales en Materia de Invenciones y Diseños Industriales (Documento preparado por la Oficina Internacional de la OMPI a solicitud de la Comisión de Propiedad Intelectual del MERCOSUR), Geneva: may 1994

WIPO Records of the Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as far as Patents are Concerned - Volume I: First Part of the Diplomatic Conference, The Hague, 1991, Geneva: WIPO (1991)

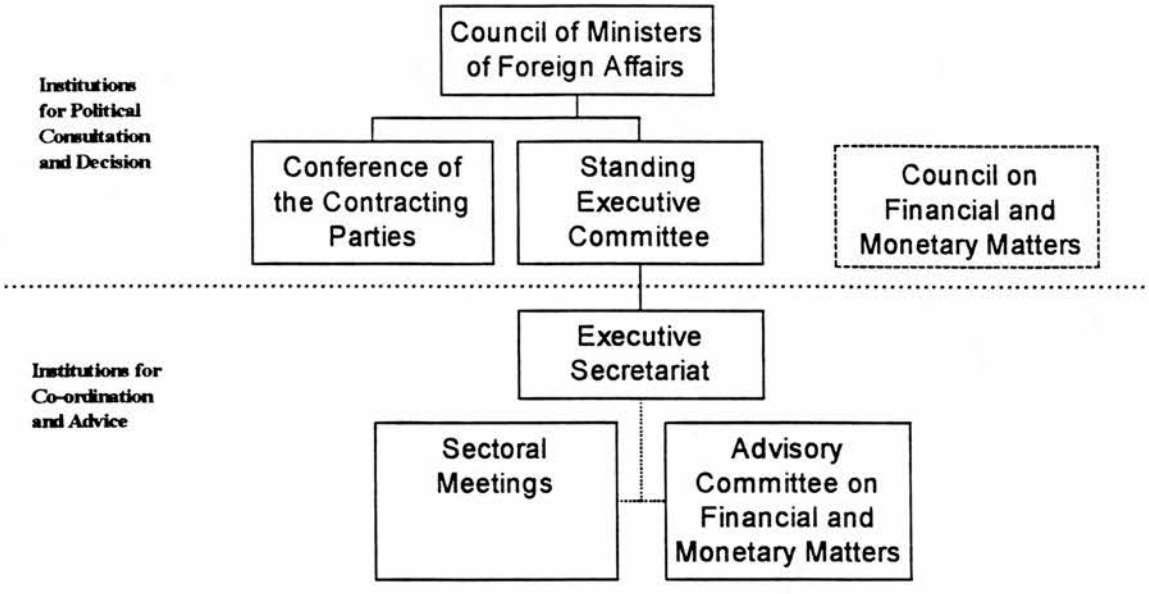
WIPO Reunion de Expertos Gubernamentales Sobre Propiedad Intelectual en los Paises del MERCOSUR, Organizado por la OMPI en Coordinación con el Grupo Mercado Común del MERCOSUR y la Asistencia del Programa de las Naciones Unidas para el Desarrollo (14-15 Março 1994), Document N. OMPI/MERCOSUR/MVD/94/2 (March 1994)

WIPO States Party to the Convention Establishing the World Intellectual Property Organization (WIPO) and/or the Other Treaties Administered by WIPO and/or to the International Convention for the Protection of New Varieties of Plants (UPOV) - Governing Bodies of WIPO, of the Unions Administered by WIPO and their (Permanent) Committees, and of the Rome Convention, Document N. 423 (E) (1 January 1996)

APPENDIX I

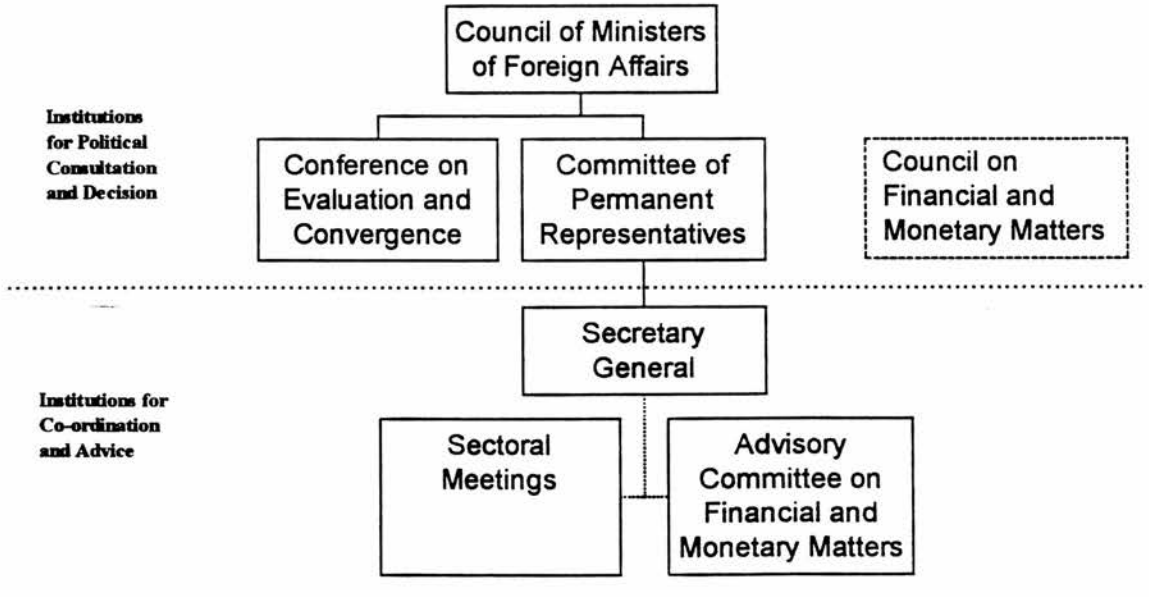
CHARTS: CHAPTER 1

Chart 1: Latin American Free Trade Association (LAFTA)



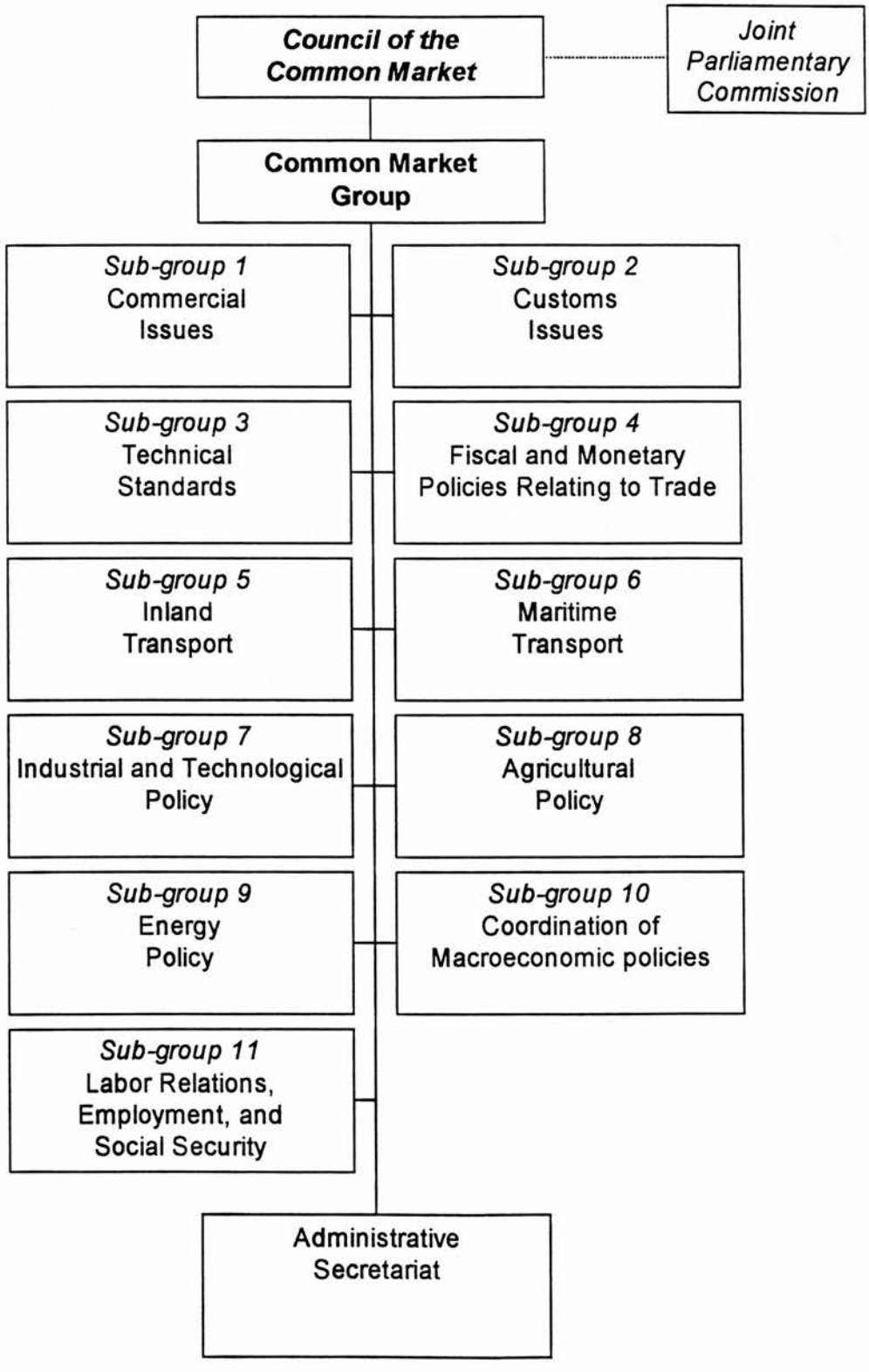
Source: **IDB & INTAL**, Economic and Social Progress In Latin America: Economic Integration (1984 report), Washington, DC: Inter-American Development Bank (1984), p. 42, was used as a reference for the present chart.

Chart 2: Latin American Integration Association (LAIA)



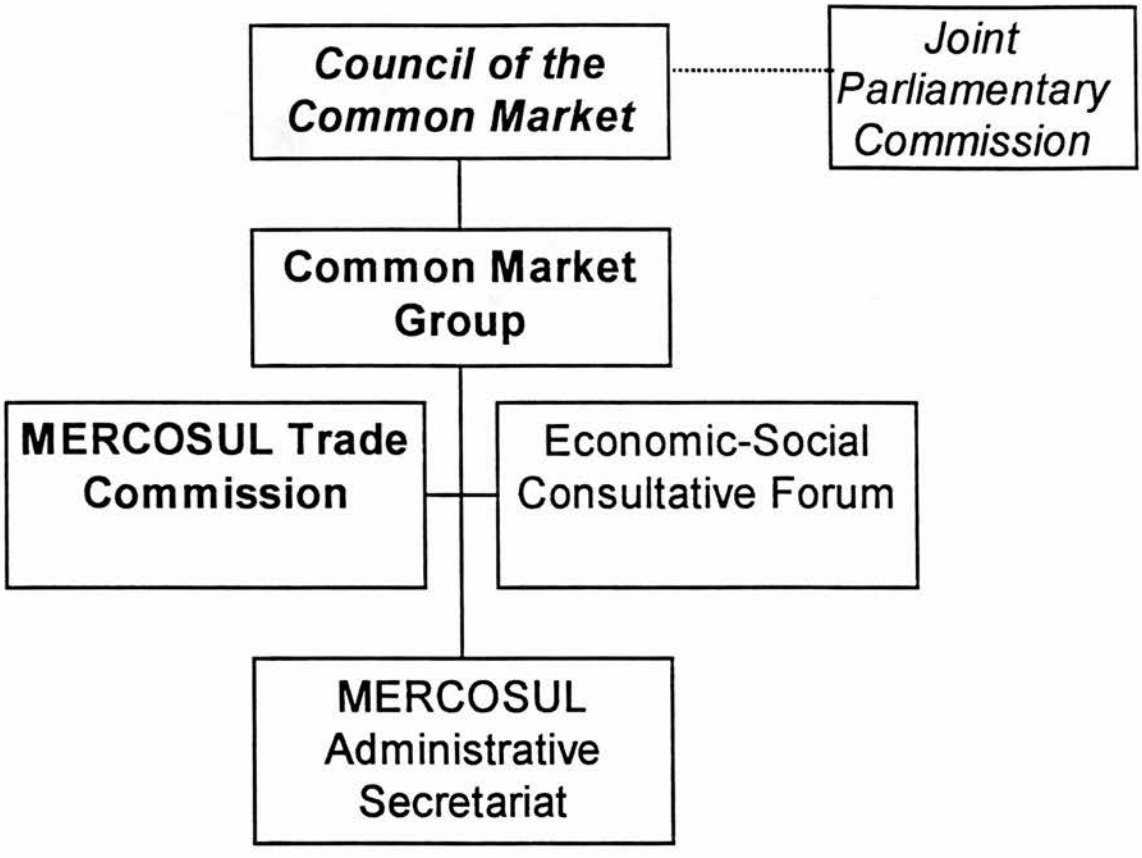
Source: **IDB & INTAL**, Economic and Social Progress In Latin America: Economic Integration (1984 report), Washington, DC: Inter-American Development Bank (1984), p. 42

Chart 3: Common Market of the South (MERCOSUL) - Treaty of Asuncion



In bold characters are the organs with decision-making powers

Chart 4: Common Market of the South (MERCOSUL) - Ouro Preto Protocol



In bold letters are the organs with decision-making powers

APPENDIX II
CHARTS: CHAPTER 2

Chart 1: World Intellectual Property Organization (WIPO)

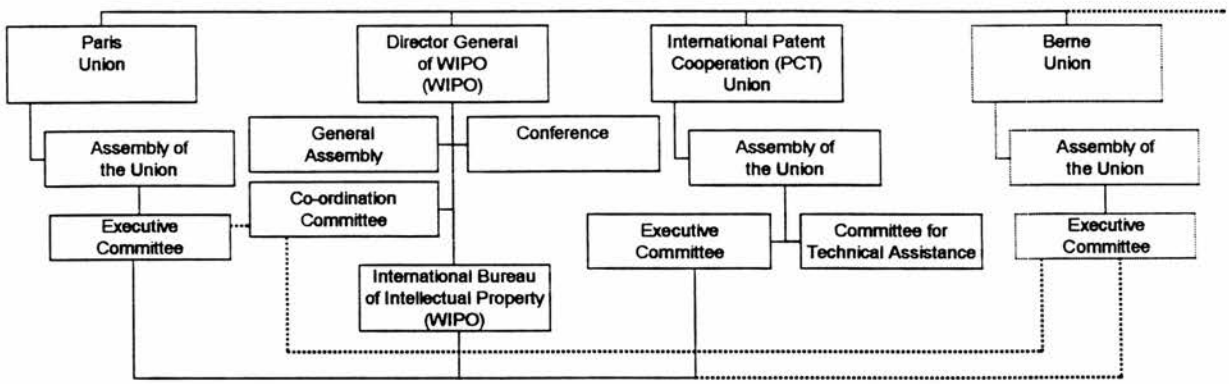
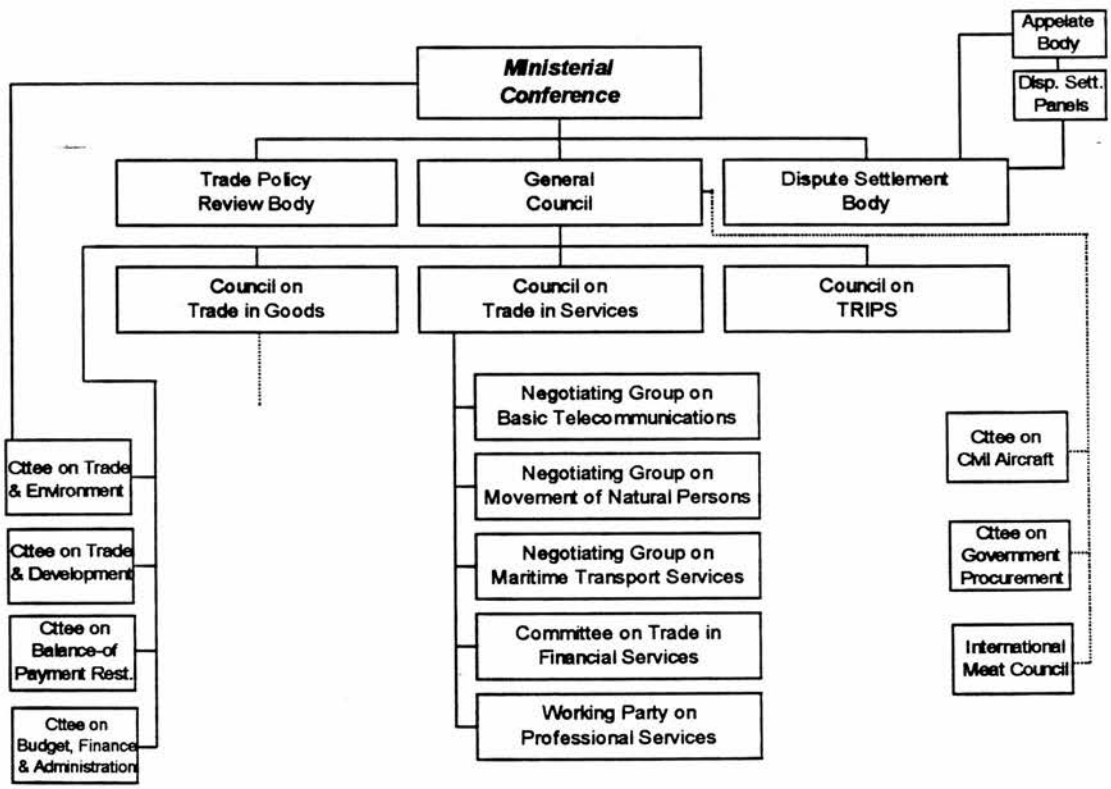


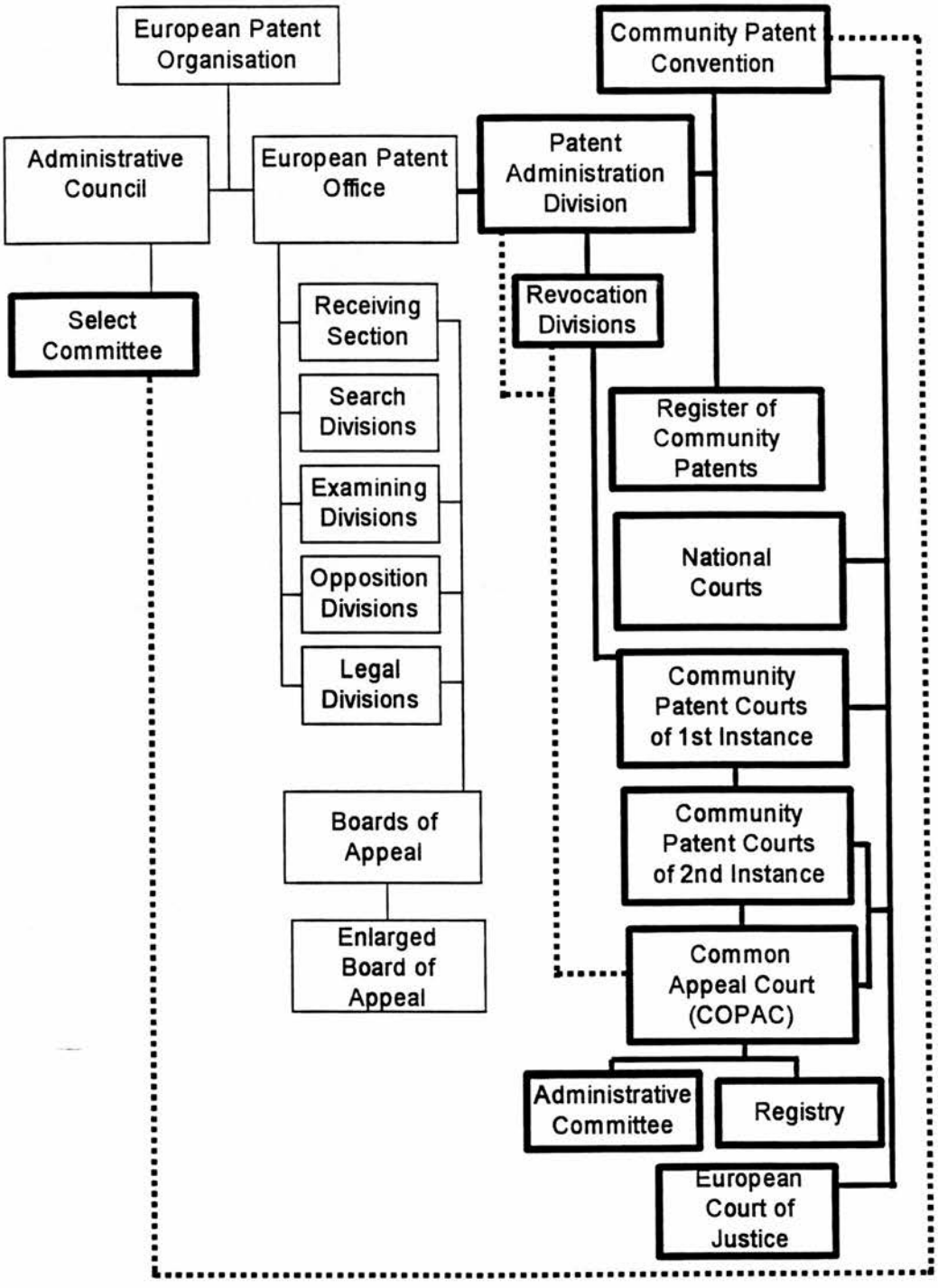
Chart 2: World Trade Organization (WTO)



Source: WTO Focus, n. 1, January/February 1995, p. 5

APPENDIX III

THE INTERACTION BETWEEN THE EPC AND THE CPC



The chart in bold represents the main structure of the CPC, which would work in harmony with the main structure of the EPC

APPENDIX IV

BIOTECHNOLOGY PATENTS IN BRAZIL

Box 1 **(Occurrence of patent applications in Brazil - per area of application - in the field of new biotechnology, in particular genetic engineering or mutations - published in the last 10 years)**

1980/1990

Total of applications = 146

Percentage	Field	Types
41,10%	Health	- Antibiotics - Hormones - Vaccines - Diagnosis - "Interferons", etc.
26,02%	Agriculture	- Pesticides - Tissue cultures - Protoplast fusion - DNA prospecting, etc.
7,54%	Foodstuffs	- Proteins and other products
10,95%	Intermediaries	- Plasmideos - Vectors, etc.
14,39%	Others	- Mining - Energy - Prospection of petrol - Environment - General techniques, etc.

Source: INPI

Box 2 **(Distribution of patent applications in Brazil - per country of origin - in the field of new biotechnology, in particular genetic engineering or mutations - applications published in the last 10 years)**

1980/1990

Total of applications = 146

United States	48,63%
Switzerland	13%
United Kingdom	8,22%
The Netherlands	8,22%
Japan	6,16%
France	4,11%
Brasil	2,74%
Denmark	2,74%
Others (Austria, Germany, Belgium, Sweden, South Africa, Panama)	6,18%

Source: INPI

APPENDIX V

LEGAL COMPONENTS OF THE TRRs CONCEPT

Prepared by the "Working Group on Traditional Resources Rights"
Oxford Centre for the Environment, Ethics & Society
Mansfield College
University of Oxford
Oxford OX1 3TF
Tel/Fax: 01865-284665
Email: wgtrr.ocees@mansfield.oxford.ac.uk

BUNDLE OF RIGHTS	SUPPORTING AGREEMENTS: Legally binding	SUPPORTING AGREEMENTS: Non-legally binding
Human rights	*ICESCR, ICCPR, CDW, CERD, CG, CRC, NLs*	*UDHR, DDRIP, VDPA*
Right to self-determination	*ILO 169, ICESCR, ICCPR*	*DDRIP, VDPA*
Collective rights	*ILO 169, ICESCR, ICCPR*	*DDRIP, VDPA*
Land and territorial rights	*ILO 169, NLs*	*DDRIP*
Right to religious freedom	*ICCPR, NLs*	*UDHR*
Right to development	*ICESCR, ICCPR, ILO 169*	*DDHRE, DDRIP, DHRD, VDPA*
Right to privacy	*ICCPR, NLs*	*UDHR*
Prior informed consent	*CBD, NLs*	*DDRIP*
Environmental integrity	*CBD*	*RD, DDHRE*
Intellectual property rights	*CBD, WIPO, GATT, UPOV, NLs*	
Neighbouring rights	*RC, NLs*	
Right to enter into legal agreements, such as contracts and covenants	*NLs*	
Cultural property rights	*UNESCO-CCP, NLs*	
Right to protection of folklore	*NLs*	*UNESCO-WIPO, UNESCO-F*
Right to protection of cultural heritage	*UNESCO-WHC, NLs*	*UNESCO-PICC*
Recognition of cultural landscapes	*UNESCO-WHC*	
Recognition of customary law and practice	*ILO 169, NLs*	*DDRIP*
Farmers' rights		*FAO-IUPGR*

INTERNATIONAL AGREEMENTS SUPPORTING THE TRR CONCEPT

Legally binding agreements in force

CBD	Convention on Biological Diversity (1992)
CDW	Convention on the Elimination of all Forms of Discrimination Against Women (1979)
CERD	Convention on the Elimination of all Forms of Racial Discrimination (1966)
CG	Convention on the Prevention and Punishment of the Crime of Genocide (1948)
CRC	Convention on the Rights of the Child
GATT	Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (1994)
ICESCR	UN International Covenant on Economic, Social and Cultural Rights (1966)
ICCPR	UN International Covenant on Civil and Political Rights (1966)
ILO 169	International Labour Organisation Convention 169: Convention Concerning Indigenous and Tribal Peoples in Independent Countries (1989)
NLs	National laws
RC	Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (1961)
UNESCO-WHC	UNESCO Convention Concerning the Protection of the World Cultural and Natural Heritage (1972)
UNESCO-CCP	UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (1970)
UPOV	International Convention for the Protection of New Varieties of Plants (1961, revised in 1972, 1978 and 1991)
WIPO	The World Intellectual Property Organisation, which administers international IPRs agreements, such as:

The International (Paris) Convention for the Protection of Industrial Property (1883, revised most recently in 1967)

The International (Berne) Convention for the Protection of Literary and Artistic Works (1886, revised most recently in 1971)

The Madrid Agreement Concerning the International Registration of Trademarks (1891, revised most recently in 1967)

The Lisbon Agreement for the Protection of Appelations of Origin and their International Registration (1958, revised most recently in 1967)

The Patent Cooperation Treaty (1970)

Non-legally binding agreements

DDHRE	UN Draft Declaration of Principles on Human Rights and the Environment (1994)
DDRIP	UN Draft Declaration on the Rights of Indigenous Peoples (formally adopted by the UN Working Group on Indigenous Populations in July 1994)
DHRD	UN Declaration on the Human Right to Development
FAO-IUPGR	FAO International Undertaking on Plant Genetic Resources (1987 version)
RD	Rio Declaration (1992)
UDHR	Universal Declaration of Human Rights (1948)
UNESCO-F	UNESCO Recommendations on the Safeguarding of Traditional Culture and Folklore (1989)
UNESCO-PICC	UNESCO Declaration on the Principles of International Cultural Cooperation (1966)
UNESCO-WIPO	UNESCO-WIPO Model Provisions for National Laws on Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions (1985)
VDPA	UN Vienna Declaration and Programme of Action (1993)

APPENDIX VI

LIST OF OFFICIALS AND PROFESSIONALS WHO PROVIDED SUPPORT FOR THE RESEARCH

Interviews

- Adrian Otten (Director, Intellectual Property and Investment Division, WTO, Geneva/Switzerland)
- Barry Greengrass (Secretary-General, UPOV Convention, Geneva/Switzerland)
- Bráulio de Souza Dias (Co-ordinator-General, Biodiversity Programme, Ministry of Environment, Brasília/Brazil)
- Eduardo Ariboni (Lawyer, São Paulo/Brazil)
- Ernesto Rubio (Director, Development Cooperation and External Relations Bureau for Latin America and the Caribbean, WIPO, Geneva/Switzerland)
- Fernando Gomez Carmona (Co-ordinator, Centre of International Studies, Fundação Getúlio Vargas, São Paulo/Brazil)
- Francisco Adalberto Nóbrega (Federal Public Attorney, Brasília/Brazil)
- Gabriel Francisco Leonardos (Lawyer, Rio de Janeiro/Brazil)
- Gordon Sheperd (Director of Campaigns and Treaties, WWF, Gland/Switzerland)
- Hélio Fabbri Jr. (Lawyer, São Paulo/Brazil)
- Jeffrey MacNelly (Co-ordinator, Biodiversity Programme, The World Conservation Union (IUCN), Gland/Switzerland)
- José Antonio Faria Correa (Lawyer, Rio de Janeiro/Brazil)
- José Francisco Rezek (Judge, Federal Supreme Court, Brasília/Brazil)
- José Roberto D'Affonseca Gusmão (Lawyer and former President of the INPI, São Paulo/Brazil)
- Julian Burger (Centre for Human Rights, United Nations, Geneva/Switzerland)
- Laércio Betiol (Professor, Fundação Getúlio Vargas, São Paulo/Brazil)
- Luiz Antonio Barreto de Castro (Secretary of Programme Co-ordination, Ministry of Science and Technology, Brasília/Brazil)
- Luiz Leonardos (Lawyer, Rio de Janeiro/Brazil)
- Maria Thereza Wolff (Private Patent Examiner, Rio de Janeiro/Brazil)
- Mauro Fernando Maria Arruda (General Co-ordinator, Institute of Industrial Development Studies and former President of INPI, São Paulo/Brazil)
- Michel P. Pimbert (Director, Biodiversity Programme, WWF, Gland/Switzerland)
- Newton Silveira (Lawyer, São Paulo/Brazil)

- Octavio Gallotti (President, Federal Supreme Court, Brasília/Brazil)
- Werter R. Faria (President, Brazilian Association for Studies on Integration, Porto Alegre/Brazil)

Other Support

- Antonio J.C. Antunes (Secretary-General, LAIA, Montevideo/Uruguay)
- Bruno Bath (Brazilian Diplomat, Brazilian Embassy, London/UK)
- Celso Amorim (Brazilian Ambassador, Brazilian Permanent Mission to the UN, New York/USA)
- Graça Carrion (Diplomat, Brazilian Ministry of Foreign Affairs, Brasília/Brazil)
- José Graça Aranha (Consultant, Development Cooperation and External Relations Bureau for Latin American and Caribbean, WIPO, Geneva/Switzerland)
- José Júlio dos Reis (Chief of Cabinet of the Presidency, Federal Supreme Court, Brasília/Brazil)
- Kalemani Mulongoy (Senior Programme Officer - Biotechnologist, Interim Secretariat of the Convention on Biological Diversity, Geneva/Switzerland)
- Luciana Goulart de Oliveira (Technical Co-operation Division, INPI, Rio de Janeiro/Brazil)
- Luiz Cláudio Marinho (Director, Latin American and Caribbean Economic Committee, United Nations, Santiago/Chile)
- Octavio Espinosa (Senior Counsellor, Developing Countries (Industrial Property Law) Division, WIPO, Geneva/Switzerland)
- Otávio Brandelli (Brazilian Diplomat, Ministry of Foreign Affairs, Brasília/Brazil)
- Paulo Roberto de Almeida (Brazilian Diplomat, Ministry of Foreign Affairs, Brasília/Brazil)
- Ricardo Sateler (Assistant Legal Counsel, WIPO, Geneva/Switzerland)
- Roberto Jaguaribe (Brazilian Diplomat, Brazilian Permanent Mission, Geneva/Switzerland)
- Rubens Antonio Barbosa (Brazilian Ambassador, Brazilian Embassy, London/UK)
- Susan H. Bragdon (Senior Programme Officer - Legal Adviser, Interim Secretariat of the Convention on Biological Diversity, Geneva/Switzerland)
- Victor Luiz do Prado (Brazilian Diplomat, Brazilian Permanent Mission, Geneva/Switzerland)